

A Product Stewardship Plan

For Unwanted Medicine from Households

San Mateo County, California April 15, 2019

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I. Introduction

MED-Project LLC ("MED-Project"), on behalf of the participating companies identified in <u>Appendix A</u>, submits this Product Stewardship Plan ("Plan") for Unwanted Medicine in compliance with the County of San Mateo Safe Medicine Disposal Ordinance, San Mateo County Ordinance Code 4.116.010 – 4.116.190 ("Ordinance"). The Ordinance requires pharmaceutical Producers¹ to develop a Product Stewardship Program to finance and manage the collection, transportation, and disposal of Unwanted Medicine from San Mateo County Residents.

II. Contact Information

The primary contact person for MED-Project is:

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III. Plan Definitions

Board of Pharmacy is the California State Board of Pharmacy.

Call Center is the MED-Project call center for Residents, which can be reached by callers at the toll-free number of 1-844-MED-PROJECT or 1-844-633-7765 (TTY: 711).

Carrier is the common carrier used to transport Unwanted Medicine.

County means the County of San Mateo, California.²

DEA is the U.S. Drug Enforcement Administration.

DEA Rule is the DEA Final Rule, "Disposal of Controlled Substances," 79 Fed. Reg. 53520 *et seq.*, adopted on September 9, 2014.

DOT is the U.S. Department of Transportation.

FDA is the U.S. Food and Drug Administration.

Help Desk is the MED-Project call center and email-in database for Kiosk Drop-Off Sites, Mail-Back Distribution Locations, libraries, fire states, and Department staff that can be reached by callers at a toll-free number and/or by email at sanmateocounty@med-project.org.

Host-Assisted Collection Kiosk Drop-Off Site is a location that is accessible to the public, hosting a MED-Project kiosk for the collection of Unwanted Medicine, where boxes and inner liners will be removed from kiosks, sealed, and packaged by the Host-Assisted Collection Kiosk Drop-Off Site employees.

¹ All capitalized terms used but not otherwise defined herein shall have their respective meanings set forth in the Ordinance.

² This Plan does not apply to any incorporated areas of San Mateo County where the governing body of that incorporated area has authorized its own local health officer or environmental director to administer and enforce the provisions of California Health and Safety Code § 117800, *et seq.*

Host-Assisted Collection Kiosk Drop-Off Site Host is the designated contact person or persons at the Host-Assisted Collection Kiosk Drop-Off Site.

Inhaler Mail-Back Services is the provision of pre-paid, pre-addressed packages for the collection and disposal of inhalers ("**Inhaler Mail-Back Packages**") by Vendor.

Injector Mail-Back Services is the provision of pre-paid, pre-addressed, FDA-cleared sharps containers for the collection and disposal of Pre-filled Injector Products ("**Injector Mail-Back Packages**") by Vendor.

Kiosk Drop-Off Site is a location that is accessible to the public, hosting a MED-Project kiosk for the collection of Unwanted Medicine.

Kiosk Drop-Off Site Host is the designated contact person or persons at the Kiosk Drop-Off Site.

Law Enforcement Agency or LEA is a federal, state, tribal, or local law enforcement office or agency.

Mail-Back Distribution Location is a site that is accessible to the public, such as a fire station or library, that provides MED-Project Standard Mail-Back Packages to Residents.

Mail-Back Services is the provision of pre-paid, pre-addressed containers, envelopes, or packages ("**Mail-Back Packages**") for the collection and disposal of Unwanted Medicine.

MED-Project Website is the Internet website located at www.med-project.org or www.medproject.org.

Plan or **Product Stewardship Plan** is the product stewardship plan presented in this submittal by MED-Project.

Pre-filled Injector Products are pre-filled injector products with a retractable or otherwise securely covered needle where medicine cannot be removed from them or where they contain more than trace amounts of Covered Drugs.

Program or Product Stewardship Program is the product stewardship program set forth in this Plan.

Required Languages are English, Spanish, Chinese, and Tagalog (Filipino).

Residents means human beings residing in the County. "Residents" does not include business generators of pharmaceutical waste, such as hospitals, clinics, doctor's offices, veterinary clinics, pharmacies, or airport security and law enforcement drug seizures.

Service Convenience Goals are the goals established in Ordinance § 4.116.050(b)(1).

Service Technicians are personnel trained to service Program kiosks.

Standard Mail-Back Services is the provision of pre-paid, pre-addressed envelopes for the collection and disposal of Unwanted Medicine ("**Standard Mail-Back Packages**") by Vendor.

Take-Back Event is a one-day event at a location accessible to the public, conducted by MED-Project, with oversight by law enforcement, for the collection of Unwanted Medicine from Residents.

Technician-Assisted Collection Kiosk Drop-Off Site is a location hosting a MED-Project kiosk for the collection of Unwanted Medicine that is accessible to the public where boxes and inner liners will be removed from kiosks, sealed, and packaged by Service Technicians.

Technician-Assisted Collection Kiosk Drop-Off Site Host is the designated contact person or persons at the Technician-Assisted Collection Kiosk Drop-Off Site.

Unwanted Medicine is defined in Section IV of this Plan.

Vendor is any vendor retained by MED-Project to carry out its obligations under the Program.

IV. Unwanted Medicine³

For the purposes of the Plan, "Unwanted Medicine" includes all materials identified as "Covered Drugs" under Ordinance § 4.116.020(D) that qualify as Covered Drug[s]" under Ordinance Section 4.116.020(V). According to the Ordinance, Covered Drugs means "a Drug in any form used by County residents, including prescription, nonprescription, brand name and generic drugs." Ordinance § 4.116.020(D). Unwanted Medicine does not include the following:

- i. Expired undispensed samples direct from physicians' offices;
- ii. Unused or expired drugs from hospitals and institutions;
- iii. Bulk animal pharmaceuticals from farms (business use);
- iv. Vitamins or supplements;
- v. Herbal-based remedies and homeopathic drugs, products, or remedies;
- vi. Compressed cylinders and mercury containing thermometers;
- vii. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. Chapter 9);
- viii. Hard surface and toilet disinfectant cleaners;
- ix. Drugs administered in a healthcare setting;
- x. Drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration managed risk evaluation and mitigation strategy (Title 21 U.S.C. § 355-1);
- xi. Drugs that are biological products, meaning any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man, as these terms are defined by 21 C.F.R. § 600.3(h), if the Producer already provides a pharmaceutical product stewardship or take-back program;
- xii. Medical devices or their component parts or accessories;
- xiii. Used, empty containers, vials, and pouches that do not contain a usable quantity of covered drugs; and
- xiv. Schedule I or other illicit drugs.

See Section XIV.A for collection limitations imposed by the DEA Rule.

V. Collection of Unwanted Medicine

The Plan provides services to collect Unwanted Medicine, including controlled substances, in any dosage form. The collection methods and applicable legal requirements are described below.

A. Unwanted Medicine Collection Program Implementation

1. Outreach

Per Ordinance § 4.116.030(e)(2), MED-Project initially notified 115 sites with a licensed pharmacy and 24 LEA locations in the County of the opportunity to participate as a Kiosk Drop-Off Site. MED-Project continues to perform outreach via annual notification letters to potential Kiosk Drop-Off Sites with the goal of establishing Kiosk Drop-Off Sites distributed throughout the County. As part of this outreach, MED-Project asks if the sites are interested in participating in the Program, whether the sites currently host a kiosk or provide other services for the disposal of Unwanted Medicine, whether pharmacies are DEA registrants, and if the sites would like more information regarding the Program.

³ Unwanted Medicine collected at Kiosk Drop-Off Sites, in Standard Mail-Back Packages, and/or at Take-Back Events does not include Pre-filled Injector Products. In addition, inhalers cannot be accepted in Standard Mail-Back Packages.

LEAs and pharmacies that hosted kiosks in the County prior to the Program may transition to the Program upon entering into an agreement with MED-Project.

2. Implementation

MED-Project satisfies the Service Convenience Goals through executed agreements with Kiosk Drop-Off Site Hosts. MED-Project will satisfy the Service Convenience Goals in any Supervisorial District in which signed agreements have not been attained for the minimum number of Kiosk Drop-Off Sites through Mail-Back Distribution Locations. *See* Section V for details on how MED-Project will satisfy the Service Convenience Goals.

Collection of Unwanted Medicine begins at Kiosk Drop-Off Sites once agreements have been executed with each location, kiosks have been installed, sites have been trained, and, in the case of pharmacies, all requirements of the DEA and Board of Pharmacy have been met.

3. Convenience

Per Ordinance § 4.116.050(b)(1), MED-Project will strive to establish at least one Kiosk Drop-Off Site in each Supervisorial District for every 20,000 Residents, geographically distributed to provide reasonably convenient and equitable access for all Residents. MED-Project will work to establish a minimum of five (5) Kiosk Drop-Off Sites in each Supervisorial District.

In Supervisorial Districts where a sufficient number of Kiosk Drop-Off Sites cannot be established, Mail-Back Distribution Locations and/or Take-Back Events will be established in order to supplement the disposal of Unwanted Medicine by Residents. As MED-Project obtains additional agreements with Kiosk Drop-Off Site Hosts, these supplemental services will decrease.

Standard Mail-Back Services will be available to disabled and home-bound Residents upon request and will be reviewed routinely for availability and effectiveness. *See* Section V.E for more information about the availability of Mail-Back Services.

In addition to the Kiosk Drop-Off Sites and Mail-Back Distribution Locations as outlined above, MED-Project shall jointly operate a Kiosk Drop-Off Site within each County-owned pharmacy with all other approved stewardship plans.

4. Services

MED-Project will assess performance, gauge feedback, and revise its approach as appropriate. As implementation proceeds, MED-Project shall continue outreach to organizations that may be available as future Kiosk Drop-Off Sites on an annual basis, such as those listed in Appendix B.

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations. Over the course of implementation, additional Kiosk Drop-Off Sites will be established to the extent that (1) additional eligible LEAs and/or DEA-registered collector pharmacies agree to participate, and (2) contracts can be executed with such entities. MED-Project will establish Mail-Back Distribution Locations for underserved areas. For every engagement with LEAs and pharmacies establishing Kiosk Drop-Off Sites, and/or conducting of Take-Back Events, contracts outlining the responsibilities of all involved parties will be drafted, reviewed by appropriate entities, and signed by all parties before MED-Project installs kiosks and/or conducts Take-Back Events.

Although Kiosk Drop-Off Sites will not provide kiosk collection for Pre-filled Injector Products, Injector Mail-Back Services for Pre-filled Injector Products will be available through the Call Center and MED-Project Website for all Residents.

MED-Project will inform the Department of any changes to Kiosk Drop-Off Sites, Take-Back Events, and/or Mail-Back Distribution Locations and Program services according to the Ordinance.

B. Kiosk Drop-Off Sites

Kiosk Drop-Off Sites will be strategically placed throughout the County in order to best meet the Service Convenience Goals established by the Ordinance. All Kiosk Drop-Off Sites shall provide Residents with access to Program kiosks during regular business hours.

1. Kiosk Drop-Off Site Locations

MED-Project initially contacted 24 LEAs and 115 sites with a licensed pharmacy located in the County about the opportunity to serve as a Kiosk Drop-Off Site. MED-Project outreach to sites began with a letter to potential collection sites in February 2016, informing the sites of the upcoming Program, followed by calls, emails, and faxes to sites that did not respond to the letter. Upon receipt of the Notice of Determination issued in September 2016 from the County, MED-Project performed additional outreach in Q4, 2016 using a combination of letters, faxes, emails, and phone calls to potential sites. Potential sites were separated into LEA, independent pharmacy, hospitals/clinics with an onsite pharmacy, and chain pharmacy categories. Chain pharmacies and health systems were approached at the headquarters level based upon the presence of sites across multiple jurisdictions.

Method of Contact Summary

2016	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Letters		~								~	~	~
Fax										~	~	~
Email										~	~	~
Phone Calls										~	~	~
Site Visits											~	~

All independent pharmacies and LEAs had multiple methods of contact in 2017. This phase of the outreach campaign sought to familiarize sites with the Program and MED-Project, followed by phone calls and emails focused on recruiting interested sites and distributing agreements. In-person site visits began once specific points of contact at potential sites were determined. Where possible, MED-Project partnered with the County to educate and encourage potential sites to participate.

Of the locations contacted, 21 LEAs and 36 pharmacies expressed interest or are participating in the Program. Kiosk Drop-Off Sites that currently participate or are interested in participating in the Program as of April 15, 2019 are identified in Appendix C.

MED-Project will continue outreach to potential Kiosk Drop-Off Sites that are not participating in the Program, such as sites listed in <u>Appendix D</u>, via annual notification letters are sent to nonparticipating or new Retail Pharmacies, according to requirements in Ordinance Section 4.116.030(e)(2).

MED-Project will establish Mail-Back Distribution Locations in any Supervisorial District where there are fewer than the required number of Kiosk Drop-Off Sites. *See* Section V.E for more information on Mail-Back Services.

As required under Ordinance § 4.116.050(b)(4), the Plan will include as a Kiosk Drop-Off Site any eligible retail pharmacy or LEA willing to serve voluntarily as a Kiosk Drop-Off Site for Unwanted Medicine and able to meet all applicable laws, regulations, and other legal requirements within three months of their offer to participate.

2. Drop-Off Site Kiosk Placement and Maintenance Program

Kiosk installation shall be the responsibility of MED-Project at Kiosk Drop-Off Sites when the Kiosk Drop-Off Site Host has identified a compliant placement location. All kiosks in the Program must be securely placed and maintained inside a collector's registered location or LEA's physical location in accordance with DEA Rule §§ 1317.75(d)(1) and 1317.35(a). At pharmacies, kiosks will be placed in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (*i.e.*, can be seen from the counter), pursuant to § 1317.75(d)(2). At a hospital or clinic with an on-site pharmacy, kiosks will be placed in an area regularly monitored by employees but not near areas of the facility where urgent or emergency care is provided. § 1317.75(d)(2)(i). Kiosk placement will also comply with any applicable Board of Pharmacy requirements. Costs associated with installation and maintenance will be paid by MED-Project per the contracts with the Kiosk Drop-Off Site Hosts.

The maintenance program will address items such as:

- Service Technician(s) will inspect the kiosk during kiosk collection service and escalate issues for maintenance as needed. The inspection will include the functionality of mechanisms, such as the locks, doors, and drop-slots.
- Reporting by the Kiosk Drop-Off Site Host of damage to a kiosk or requested maintenance service.
 A summary of the requested maintenance log will be available upon request.

Vendor will respond within two to three business days of a requested maintenance service unless the requested service requires a Rapid Response. *See* Section V.B.7.

3. Kiosk Specifications

A kiosk will be offered to all eligible host locations. Pursuant to § 1317.75(e), MED-Project kiosks at pharmacies will:

- Be securely fastened to a permanent structure;
- Be securely locked, substantially constructed containers with a permanent outer container and removable inner liner:
- Include a small opening in the outer container that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;
- Prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances are acceptable to be placed in the kiosk; and
- Have the small opening in the outer container locked or made inaccessible to the public when a Kiosk Drop-Off Site employee is not present.

The design of the pharmacy kiosk and signage (<u>Appendix E</u>) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the drop-slot; a tamper-resistant slot; and commercial hinges. The design will increase the likelihood of consumer participation by providing easy access to wheelchair-bound users. The locking mechanism on the drop-slot will prevent kiosk overflow once the container has reached its maximum level and is locked by the Kiosk Drop-Off Site Host. MED-Project pharmacy kiosks will come with appropriate regulatory signage and instructions, including an instruction to remove personal information from any Unwanted Medicine and

⁴ As discussed in Section XI, if applicable, MED-Project will coordinate with other approved product stewardship plans to develop clear standardized instructions for Residents to use kiosks and a consistent design. <u>Appendix E</u> provides the kiosk design and signage MED-Project expects to propose when coordinating with other approved product stewardship plans.

packaging before depositing them and language required under the DEA Rule⁵ and by the Board of Pharmacy. Kiosk signage will provide information about what is and is not accepted in the kiosk.

Additionally, under § 1317.60(a), MED-Project kiosk inner liners will:

- Be waterproof, tamper-evident, and tear-resistant;
- Be removable and sealable immediately upon removal without emptying or touching kiosk contents:
- When sealed, make the contents of the inner liner not viewable from the outside;
- Clearly indicate the size of the inner liner; and
- Bear a permanent, unique identifier for tracking purposes.

MED-Project kiosks and inner liners will also comply with Board of Pharmacy requirements.

While the DEA Rule does not require LEA kiosks to meet these same requirements, MED-Project will offer these kiosks and inner liners to LEAs. See DEA Rule at 53531.

4. Kiosk Collection

Under § 1317.05(c)(2)(iv), pharmacy Kiosk Drop-Off Site Hosts must dispose of sealed inner liners and their contents either on-site, through common or contract carrier delivery to, or pick-up by, a reverse distributor or distributor, or with DEA assistance.

Section 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, § 1317.60 limits inner liner access to employees of the collector and requires two employees to immediately seal the inner liner upon its removal from the pharmacy kiosk's permanent outer container. See § 1317.60(b), (c). Section 1317.75(g) provides that pharmacy kiosk inner liner installation or removal shall be performed "by or under the supervision of at least two employees of the authorized collector." The pharmacy kiosk sealed inner liner must not be opened, x-rayed, analyzed, or otherwise penetrated. See § 1317.60(c).

At LEA Kiosk Drop-Off Sites, Vendor and the LEA will maintain any records of removal, storage, or destruction of the collected Unwanted Medicine in a manner consistent with the LEAs' recordkeeping requirements for illicit controlled substances evidence pursuant to § 1317.35. LEAs will record the unique identifier and size of the sealed inner liner transferred to Vendor. See § 1317.35. Additionally, any Unwanted Medicine will be stored in a manner to prevent the diversion of controlled substances and consistent with the LEA's standard procedures for storing illicit controlled substances. See § 1317.35. Collected Unwanted Medicine will be transferred to the disposal facility in a manner to prevent the diversion of Unwanted Medicine and consistent with the LEA's standard procedures for transferring illicit controlled substances. See § 1317.35.

MED-Project's Kiosk Drop-Off Site collection system complies with these DEA requirements for pharmacy and LEA Kiosk Drop-Off Sites. Vendor, pharmacies, and LEAs participating in the Program will keep all records required under the DEA Rule, including those required under §§ 1304 and 1317.35. Pharmacies participating in the Program will also keep all records required under Board of Pharmacy requirements. Pharmacy Kiosk Drop-Off Site Hosts and Vendor will be instructed never to count, sort, inventory, or individually handle kiosk contents.

Pharmacy kiosks will be located where an employee is present, affording employees the opportunity to visually inspect Unwanted Medicines Residents attempt to deposit. See Section V.B.2. LEA kiosks will be

⁵ Specifically, as required under § 1317.75(e)(4), all kiosks will prominently display a sign stating that: "Only Schedule II-V controlled and non-controlled substances that are lawfully possessed by the ultimate user are acceptable to be placed in the kiosk. Schedule I controlled substances, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk."

located inside the LEA's physical location. *See* Section V.B.2. MED-Project's Kiosk Drop-Off Site collection system will also comply with all applicable Board of Pharmacy requirements.

A Kiosk Drop-Off Site may elect to participate in the program via either the technician-assisted collection method or host-assisted collection method. If a Kiosk Drop-Off Site elects to participate via the technician-assisted collection method, a Service Technician will regularly come to the Technician-Assisted Collection Kiosk Drop-Off Site to help prepare the inner liner for shipment and disposal. If a Kiosk Drop-Off Site elects to participate via the host-assisted collection method, the Host-Assisted Collection Kiosk Drop-Off Site employees will prepare the inner liner for shipment.

Vendor will prepare the materials for shipment at Technician-Assisted Collection Kiosk Drop Off Sites and perform applicable pre-transportation functions to comply with the DOT Hazardous Materials Regulations ("HMR").

a. Technician-Assisted Collection

For Kiosk Drop-Off Sites that opt to participate via the technician-assisted collection method, pick-up of Unwanted Medicine collected at Kiosk Drop-Off Sites will be scheduled year-round based on their regular business hours and weight collected. After arriving at a Technician-Assisted Collection Kiosk Drop-Off Site, the Service Technician will check the kiosk for any damage.

The inner liner and box will be securely removed from the kiosk by a Service Technician and Technician-Assisted Collection Kiosk Drop-Off Site employees following procedures meeting all DEA requirements. Specifically, two Technician-Assisted Collection Kiosk Drop-Off Site employees will hold the two keys to unlock the kiosk. Once the kiosk is unlocked, the inner liner will be removed from the kiosk and immediately sealed. The inner liner provided in the kiosk will be opaque to prevent visual recognition of the contents. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Under the supervision of two Technician-Assisted Collection Kiosk Drop-Off Site employees, the Service Technician will seal the liner for packaging and transport. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The Service Technician will schedule a pick-up from the Carrier to be completed within three days and leave the packaged, sealed inner liner with the Technician-Assisted Collection Kiosk Drop-Off Site Host for storage in compliance with all applicable laws, regulations, and other legal requirements until Carrier pick-up.

Vendor will prepare the materials for shipment and perform applicable pre-transportation functions to comply with DOT HMR.

Any technician-assisted collection of controlled substances by LEAs will be consistent with the LEA's standard procedures for transferring illicit controlled substances. *See* DEA Rule § 1317.35.

b. Host-Assisted Collection

Host-assisted collection will enable a Host-Assisted Collection Kiosk Drop-Off Site Host to directly control the timing for servicing the kiosk by allowing the Host-Assisted Collection Kiosk Drop-Off Site Host employees to seal the liner for packaging and transport at a time of their choosing. This method will allow Host-Assisted Collection Kiosk Drop-Off Site Hosts to avoid disruptions to operations that may result from Vendor-scheduled visits or storage limitations.

Unwanted Medicine will be securely removed from the kiosk by Host-Assisted Collection Kiosk Drop-Off Site employees following procedures meeting all DEA requirements. Specifically, two Host-Assisted Collection Kiosk Drop-Off Site employees will hold the two keys to unlock the kiosk. Once the kiosk is unlocked, the inner liner will be removed from the kiosk and immediately sealed. The inner liner provided in the kiosk will be opaque to prevent visual recognition of the contents. The sealed inner liner will not be opened, x-rayed, analyzed, or otherwise penetrated.

Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site employees will seal the inner liner for packaging and transport. The unique identifier of the inner liner will be matched to the tracking number on the shipping label. The two Host-Assisted Collection Kiosk Drop-Off Site employees will either schedule a pick-up from the Carrier to be completed within three business days or offer the packaging containing the sealed inner liner for pick-up by routine Carrier service at the Host-Assisted Collection Kiosk Drop-Off Site. If the package containing the sealed inner liner is prepared prior to pick-up, the Host-Assisted Collection Kiosk Drop-Off Site Host will store the inner liner in compliance with all applicable laws, regulations, and other legal requirements until Carrier pick-up. The Carrier will transport the package to the facility designated in Section X.

Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site employees will prepare materials for shipment and perform applicable pre-transportation functions to comply with the DOT HMR.

Following instructions provided by Vendor, the two Host-Assisted Collection Kiosk Drop-Off Site employees will replace the removed inner liner and box with a replenishment inner liner and box provided by Vendor. Each inner liner and box provided by Vendor will be pre-paid and pre-addressed for transport and disposal.

Any host-assisted collection of controlled substances by LEA will be consistent with the LEA's standard procedures for transferring illicit controlled substances. *See* § 1317.35.

5. Frequency of Pick-Up

Initially, all Technician-Assisted Collection Kiosk Drop-Off Sites will be scheduled for a monthly pick-up from the kiosk. Vendor will communicate with MED-Project if the frequency of pick-up needs to be changed based on the weight collected over time. Vendor will monitor the weight per service to ensure that all sites are receiving the appropriate service frequency. Vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Technician-Assisted Collection Kiosk Drop-Off Site. Host-Assisted Collection Kiosk Drop-Off Sites will be instructed to service the kiosk and request a pick-up by Carrier, as needed.

6. Procedures if a Kiosk is Full Prior to Scheduled Pick-Up

The Technician-Assisted Collection Kiosk Drop-Off Site Host shall be instructed to lock the drop-slot to the kiosk when the kiosk is full and notify MED-Project of the need for service if prior to the scheduled service date.

Vendor shall provide a network of trained Service Technicians. Vendor will communicate service requests to field managers responsible for Service Technicians. Vendor will direct service to the trained Service Technician who is in closest proximity to the Technician-Assisted Collection Kiosk Drop-Off Site requesting the service. This process provides for a timely response to Technician-Assisted Collection Kiosk Drop-Off Sites requiring service prior to the scheduled date.

Service timelines will be assessed based on the specific characteristics of the Technician-Assisted Collection Kiosk Drop-Off Site's need. If necessary, Vendor will be able to respond within hours of the request. If the request does not require an urgent response, Vendor will respond within two to three business days of the request. In the interim, pharmacy Technician-Assisted Collection Kiosk Drop-Off Site Hosts shall be instructed to secure the kiosk and its contents in accordance with DEA requirements.

Host-Assisted Collection Kiosk Drop-Off Sites will be instructed to service the kiosk and request a pick-up by Carrier as needed.

7. Unplanned Event Preparedness

Vendor maintains a network of emergency responders that can be contacted in the case of an emergency or spill incident. Vendor ensures compliance of all service providers through a business confidential qualification process. This process reviews the compliance history, management structure, financial stability, and other key indicators of a reliable emergency response service provider. Emergency responders will bring all necessary equipment in order to manage the specific needs of the Kiosk Drop-Off Site requiring emergency response. Kiosk Drop-Off Site Hosts will be directed to call 911 in situations posing an immediate threat to the environment or health.

A major event, such as a flood, earthquake or fire, may require response by a service team. This event can jeopardize the security characteristics of the kiosk as well as the structural integrity of the participating location. The team will assess the safety of the area along with the locations to be serviced. Once it is determined the area is safe for access, the team will work to secure the kiosk and remove its contents.

Along with major event preparedness, Vendor provides timely responses to events that may cause an inconvenience to the Kiosk Drop-Off Site. An example of this kind of event would be if the kiosk is giving off an odor prior to the scheduled service date. The Kiosk Drop-Off Site Host will contact MED-Project via the dedicated Help Desk. Vendor is able to respond within two to three hours when notified of a need for emergency response. If the request is not an emergency that poses an immediate threat to the environment or health, Vendor will typically respond to a service location within two to three business days of the event.

In addition, any items that a Resident deposits into the kiosk will not be retrieved.

C. Take-Back Events

MED-Project may schedule Take-Back Events in any Supervisorial District where the Service Convenience Goals are not met through signed Kiosk Drop-Off Site agreements and/or Mail-Back Distribution Locations.

MED-Project will confirm to the County the locations and dates to conduct Take-Back Events once contracts with supervising LEAs have been executed. LEA employees shall oversee all Take-Back Events. As stated in the goals (see Section VI), it is the intention of MED-Project to conduct Take-Back Events in order to supplement Kiosk Drop-Off Sites and Mail-Back Distribution Locations as they are implemented across the County. MED-Project will select the location of the Take-Back Events based upon demographics, current Kiosk Drop-Off Sites, Mail-Back Distribution Locations and other population diversity characteristics to maximize Resident access to the events and best meet the Service Convenience Goals. In situations where a location in the community cannot be secured in a Supervisorial District, MED-Project will work with the participating LEA in that district to host the event at the precinct or other County facilities.

Due to the changing schedule of Take-Back Events, the list of dates and locations will be maintained on the MED-Project Website as events are scheduled and confirmed.

1. Method

The conducting of Take-Back Events by MED-Project is contingent upon participation and oversight by LEAs. MED-Project will work with participating LEAs to ensure Take-Back Events are compliant and successful. Events will be promoted and communicated to the public through local communication channels as outlined in Section XI.

MED-Project Take-Back Events will meet all applicable laws, regulations, and other legal requirements. MED-Project will contract with LEAs to oversee Take-Back Events. These contracts will provide for the collection, transportation, and disposal of Unwanted Medicine from Take-Back Events and ensure that all requirements of participating LEAs are met. MED-Project will work with LEAs to accommodate any reasonable requirements.

2. Procedures

MED-Project will partner with LEAs to ensure that at least one law enforcement officer oversees collection at every Take-Back Event pursuant to DEA Rule § 1317.65(a), (b). The law enforcement officers will maintain control and custody of all Unwanted Medicine collected at Take-Back Events from collection until secure transfer, storage, or destruction of the Unwanted Medicine, as required by § 1317.65(b). Only ultimate users and persons authorized to dispose of an ultimate user decedent's property in lawful possession of controlled substances in Schedules II-V may transfer these substances to the LEA during the event. No other person will handle controlled substances at Take-Back Events under § 1317.65(e); however, Vendor may assist LEAs in the collection of Unwanted Medicine at Take-Back Events. *See* DEA Rule at 53539.

Take-Back Events will typically be staffed by at least two Vendor employees. Vendor will work in coordination with MED-Project, the County, and LEAs to monitor and ensure collection of all material at Take-Back Events is compliant with all applicable laws, regulations, and other legal requirements. Vendor will work in conjunction with law enforcement to ensure all material is placed in a compliant collection receptacle and securely shipped to meet all applicable laws, regulations, and other legal requirements. Any material that is not Unwanted Medicine or does not meet legal requirements will be rejected.

Vendor and the LEA will maintain all records of collection, storage, or destruction of the collected Unwanted Medicine in a manner consistent with the LEA's recordkeeping requirements for illicit controlled substances evidence pursuant to DEA Rule § 1317.35. Any collected Unwanted Medicine will be stored to prevent the diversion of controlled substances and consistent with the LEA's standard procedures for storing illicit controlled substances. Any storage of Unwanted Medicine by Vendor will also comply with the applicable security requirements of DEA Rule §§ 1301 and 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances.

Following the completion of each event, containers will be weighed, securely packaged, labeled and shipped in compliance with all applicable laws, regulations, and other legal requirements. Containers and inner liners will be tracked at pick-up and destruction via unique identifiers and incinerated at a facility identified in Section X. Vendor will ship the containers (and inner liners) in accordance with the requirements outlined in Section XIV.B.

3. Fees and Costs

MED-Project shall pay all administrative and operational costs and fees associated with the Take-Back Events.

D. Disposal of Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events

Vendor and Carrier shall manage the Unwanted Medicine from Technician-Assisted Collection Kiosk Drop-Off Sites and Take-Back Events in compliance with all applicable laws, regulations, and other legal requirements. Carrier shall deliver Unwanted Medicine collected from all Kiosk Drop-Off Sites and/or Take-Back Events to the respective facilities identified in Section X, including at the Stericycle, Inc., Warren, Ohio Facility. MED-Project's request for approval to dispose of Unwanted Medicine from Technician-Assisted Collection Kiosk Drop-Off Sites by incineration at a medical waste incinerator is included in Appendix F.

All inner liners will be destroyed in accordance with all applicable laws, regulations, and other legal requirements at the disposal facilities identified in Section X.

Host-Assisted Collection Kiosk Drop-Off Sites will manage sealed inner liners as described in Section V.B.4(b). MED-Project proposes disposal of Unwanted Medicine from Host-Assisted Collection Kiosk Drop-

⁶ The Director previously approved Unwanted Medicine Disposal at the Stericycle Warren Ohio facility on July 3, 2018.

Off Sites by incineration at the Stericycle medical waste incinerator in Warren, Ohio and a municipal waste combustor. MED-Project's request for approval to dispose of Unwanted Medicine from Host-Assisted Collection Kiosk Drop-Off Sites by incineration at either a medical waste incinerator or a municipal waste combustor is included in Appendix F.

E. Mail-Back Services for Unwanted Medicine

MED-Project will provide three types of Mail-Back Services that will be available through the Call Center and MED-Project Website:

- Standard Mail-Back Services for Residents as described in Section V.E.1:
- Injector Mail-Back Services for the collection of Pre-filled Injector Products for all Residents as described in Section V.E.2; and
- Inhaler Mail-Back Services for the collection of inhalers for disabled and home-bound Residents as described in Section V.E.3.

1. Standard Mail-Back Services for Unwanted Medicine

MED-Project will provide Standard Mail-Back Services at no cost to disabled and home-bound Residents via the Call Center and/or MED-Project Website. Standard Mail-Back Packages will also be available at Mail-Back Distribution Locations for all Residents until the Service Convenience Goals are met via Kiosk Drop-Off Sites. The pre-paid shipping label will direct the Standard Mail-Back Package to the facility identified in Section X. Standard Mail-Back Packages for Unwanted Medicine shall comply with all applicable laws, regulations, and other legal requirements.

Pursuant to DEA Rule § 1317.70(c), the Standard Mail-Back Packages for the collection of Unwanted Medicine, not including inhalers and Pre-filled Injector Products will be:

- Nondescript and without any markings or information potentially indicating that they contain Unwanted Medicine, including controlled substances;
- Water and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with and delivered to Vendor's registered address;
- Pre-paid;
- Provided with a unique identifier enabling tracking; and
- Provided with instructions indicating the process for mailing back the packages, accepted substances, a notice about mailing restrictions, and a notice that only packages provided by Vendor will be accepted for destruction.

Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property will not be required to provide any personally identifiable information when using Standard Mail-Back Packages to dispose of Unwanted Medicine. See DEA Rule § 1317.70(d). As required under DEA Rule § 1317.70(e), Vendor will only accept Standard Mail-Back Packages it made available (or packages lawfully forwarded under DEA requirements). Within three business days of receipt, Vendor will notify the DEA if it receives Standard Mail-Back Packages likely containing controlled substances that Vendor did not make available or did not agree to receive pursuant to DEA requirements. In accordance with DEA Rule § 1317.70(f), when Standard Mail-Back Packages are received, only employees of Vendor will handle the Standard Mail-Back Packages. Standard Mail-Back Packages will not be opened, x-rayed, analyzed, or otherwise penetrated upon receipt by Vendor. See DEA Rule § 1317.70(f). Vendor will keep all records required under the DEA Rule, including those identified in DEA Rule § 1304.22(f).

2. Injector Mail-Back Services for Pre-filled Injector Products

For Pre-filled Injector Products, MED-Project will offer all Residents Injector Mail-Back Services via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Injector Mail-Back Package to the facility identified in Section X. An instruction sheet will be included with the Injector Mail-Back Package that describes how to properly dispose of Pre-filled Injector Products and explains what materials may be placed in a sharps container, how to use the sharps container, and how to return the Injector Mail-Back Package. Residents are instructed not to commingle Pre-filled Injector Products with other Unwanted Medicine.

See Appendix H for a sample package and package specifications.

3. Inhaler Mail-Back Services for Inhalers

For inhalers, MED-Project will offer disabled and home-bound Residents Inhaler Mail-Back Services via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Inhaler Mail-Back Packages to the facility identified in Section X. An instruction sheet will be included with the Inhaler Mail-Back Package that describes how to properly dispose of inhalers and explains what materials may be placed in the Inhaler Mail-Back Package, and how to return the Inhaler Mail-Back Package. Residents are instructed not to commingle inhalers with other Unwanted Medicine.

See Appendix I for sample package specifications.

4. Mail-Back Package Availability

Disabled and home-bound Residents may request Mail-Back Services by calling the Call Center and/or through a link on the MED-Project Website. Home healthcare professionals providing services to disabled and home-bound Residents may also request Mail-Back Services, on behalf of a Resident, through the Call Center and/or through a link on the MED-Project Website. Upon such request, Residents will be provided Mail-Back Packages complying with DEA requirements, if applicable.

In Supervisorial Districts where fewer than the required number of signed agreements have been met from Kiosk Drop-Off Site Hosts, MED-Project will supplement Kiosk Drop-Off Sites by establishing Mail-Back Distribution Locations for the dissemination of Standard Mail-Back Packages. MED-Project will work with facilities, such as fire stations and/or libraries, to ensure that Mail-Back Distribution Locations are conveniently located.

Injector Mail-Back Services for Pre-filled Injector Products will be available to all Residents through the Call Center and/or MED-Project Website.

All Mail-Back Services will supply packages that contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in the Required Languages. Mail-Back Packages will be shipped to Residents within seven business days of their request. Signage that can be placed in the vicinity of a MED-Project kiosk notifying Residents of the availability of Mail-Back Services is included in Appendix E.

5. Mail-Back Package Collection and Disposal

The following general procedures will be applied to the request and processing of Mail-Back Packages:

- Requests by Residents made via Call Center/MED-Project Website and are verified and logged;
- 2. Requests by Residents are processed, and tracking numbers are logged;
- 3. Mail-Back Packages are sent to requesting Residents;
- 4. Residents place Unwanted Medicine in Mail-Back Packages per instructions;
- 5. Residents place Mail-Back Packages in mail system;
- 6. Mail-Back Packages received by facility identified in Section X and unique identifier on returned Mail-Back Packages are logged as "returned";
- 7. Mail-Back Packages are disposed of; and
- 8. Information on returned Mail-Back Packages are reconciled with log of Mail-Back Packages shipped to Residents to verify type and average weight of Mail-Back Packages.

All Mail-Back Services will supply packages that contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in the Required Languages. Residents will be directed to follow the instructions provided via Mail-Back Services. Mail-Back Services shall direct packages to an approved facility in accordance with their contents and packages will be handled in compliance with all applicable laws.

For Standard Mail-Back Packages, upon arriving at the destruction facility, they shall be scanned for receipt verification and then rendered non-retrievable by incineration at the disposal facility listed in Section X. Any storage of Standard Mail-Back Packages received by Vendor will comply with the applicable security requirements of DEA Rule Section 1317, including the requirement that Unwanted Medicine is securely stored in a manner consistent with the security requirements for Schedule II controlled substances. All Unwanted Medicine will be destroyed promptly. MED-Project's request for approval for the Standard Mail-Back Package disposal process is included in Appendix J.

This Plan proposes to treat Injector Mail-Back Packages at a municipal waste combustor. *See* the facilities identified in Section X. MED-Project's request for approval for the Injector Mail-Back Package disposal process is included in Appendix K.

Inhaler Mail-Back Packages containing inhalers will be tracked upon shipment to Residents and scanned for receipt at a disposal facility for incineration using a unique identifier. The incinerator facility(ies) for the disposal of inhalers is included in Section X. MED-Project's request for approval to incinerate Inhaler Mail-Back Packages containing inhalers at a municipal waste combustor and/or a medical waste incinerator is included in <u>Appendix L</u>.

VI. Plan and Collection Goals

The short- and long-term goals of the Plan are described generally as follows. Additional detail on implementation is provided in Section V.A.2.

MED-Project anticipates that, once all Kiosk Drop-Off Sites are fully operational, the Program will collect approximately 360 pounds per Kiosk Drop-Off Site during the calendar year. Assuming 37 Kiosk Drop-Off Sites are operational for the full year, MED-Project anticipates collecting approximately 13,320 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2018. *See* Section V.B for more information about Kiosk Drop-Off Site collection.

MED-Project Standard Mail-Back Packages have a capacity of 8 oz. per package. Due to the lack of information available from current MED-Project Programs, MED-Project's estimated collection totals in 2018 could vary based on actual usage. Collection in 2018 will be used to adjust subsequent years' collection goals.

Goal Area	Short-Term	Long-Term
Collection	Within 90 days of Plan approval, implement Mail-Back Services via the MED-Project Website and Call Center. Continue to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites.	Increase retail chain pharmacy participation to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites in a minimum of four (4) out of five (5) Supervisorial Districts. Reduce or eliminate the number of Mail-Back Distribution Locations.
Education & Public Outreach	Develop baseline number of MED-Project Website page views or unique visitors. Website statistics reported in the 2017 Annual Report shall serve as the baseline for long-term goals. Establish a baseline of LEAs; retail pharmacies; other pharmacies (healthcare, etc.); community groups; and other third parties contacted, and report appropriate statistics as outlined in the Survey and Annual Report Sections of this Plan. Establish a baseline number of media outlets receiving press advisories, with a minimum of five outlets. Establish a baseline percentage of community centers reached. Establish a baseline number of messages returned by MED-Project within predetermined timeframe.	On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan. MED-Project will conduct outreach with the goal of a combined target reach of 50% at a 2+ frequency for the duration of one month, at least three times per year through a combination of digital media campaigns, print ads, and traditional broadcast media. MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the Program, assess to what extent Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Results of the review will be published on the MED-Project Website established under Section XI.D.2.
Collector Outreach	Outreach to all potential eligible Kiosk Drop-Off Site Hosts according to requirements as outlined in Ordinance Section 4.116.030(e)(2).	Ongoing communication with participating pharmacies and LEAs. Ongoing evaluation of Kiosk Drop-Off Sites against the Service Convenience Goals.

VII. Patient Privacy

Instructions at each Kiosk Drop-Off Site will inform people who deposit Unwanted Medicine that they should completely cross out, remove, or otherwise make unreadable any and all personally identifiable information on the drug containers and packaging before depositing them into the kiosk. In cases where people follow the instructions, there will be no readable personally identifiable information. Any patient information on drug containers and packaging placed into the kiosk will be promptly destroyed.

In addition to kiosk signage, all MED-Project instructional, promotional, and educational materials encourage Residents to protect their information by ensuring that personally identifiable information is not present when utilizing Mail-Back Services or depositing Unwanted Medicine into kiosks.

Vendor for Kiosk Drop-Off Sites, Take-Back Events, and Standard Mail-Back Services has additional protections available for keeping personally identifiable information safe and secure. Service Technicians are trained in managing items containing sensitive patient information. Privacy training is part of a Service Technician's prerequisite for field services. As added protection, containers, packages, and envelopes used for Mail-Back Services will be opaque rather than clear. In addition, inner liners used at Kiosk Drop-Off Sites and/or Take-Back Events will be opaque rather than clear, in compliance with the DEA Rule. This will prevent anyone, including the Service Technician, from seeing any information on the containers placed in the kiosks.

VIII. Call Center

Per Ordinance § 4.116.060, MED-Project will operate a Call Center jointly with any other approved stewardship programs operating in the County. Questions from Residents will be managed by the Call Center with the support of operators available that speak the Required Languages. When calling the Call Center, the caller will provide information to verify their residency in the County, and then will be directed to select their language of choice, such as English, Spanish, Chinese, Russian, or Tagalog, to continue.

All operators are trained to respond based on the requirements set by MED-Project. Operator training will cover all services offered by MED-Project, including helping Residents locate Kiosk Drop-Off Sites and order Mail-Back Packages for all types of Unwanted Medicine.

Operators may answer general questions, including questions on the following topics:

- 1. Items that can be disposed of;
- 2. Disposal options; and
- 3. Available Mail-Back Services.

Because the list of Kiosk Drop-Off Sites and Mail-Back Distribution Locations is subject to change, Residents will be directed to the MED-Project Website or to an operator for detailed information about locations and contact information.

IX. Training

Operational procedures, including training, are the responsibility of the Kiosk Drop-Off Site Host. MED-Project will support training if agreed to with the Kiosk Drop-Off Site Host. Additionally, MED-Project will manage a Help Desk to answer questions and monitor comments for participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations.

The Help Desk will support two general communication functions:

- 1. Answer questions and monitor comments from participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations; and
- 2. Support and direct service requests from participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations.

Any messages received by the Help Desk from Kiosk Drop-Off Sites and Mail-Back Distribution Locations will be returned within one business day.

Vendor will comply with all applicable laws, regulations, and other legal requirements. Vendor for Kiosk Drop-Off Sites, Take-Back Events, and Standard Mail-Back Services has an internal training process that includes the following:

- Onboarding & on-truck observation of job functions;
- United States Department of Transportation ("DOT") Training;
- DEA Training;
- United States Environmental Protection Agency ("EPA") Waste Characterization;
- Occupational Safety and Health Administration ("OSHA") Training;
- Waste Handling Demo;
- Truck Operation;
- DEA Handling Demo;
- Health Insurance Portability and Accountability Act ("HIPAA") requirements;
- OSHA Bloodborne Pathogens Standard;
- Review & Written Test; and
- Perform work under supervision to demonstrate proficiency prior to certification to service client accounts.

A. Service Technician Training

The Service Technicians handling Unwanted Medicine will complete comprehensive training under the direction of a Certified Hazardous Materials Manager and certified Senior Environmental Health and Safety Manager. This training includes instruction on:

- DOT hazardous materials requirements;
- EPA waste characterization requirements;
- Resource Conservation and Recovery Act ("RCRA") hazardous waste requirements;
- DEA controlled substances transfer protocols;
- OSHA requirements; and
- HIPAA requirements.

Service Technicians must complete a 24- or 40-hour Hazardous Waste Operations and Emergency Response Standard ("HAZWOPER") course. Additionally, Service Technicians must complete annual refresher training that includes an 8-hour training on DOT, HAZWOPER, HIPAA, OSHA, RCRA, and safety and security training. Finally, Service Technicians receive ongoing training in the form of daily "tips", weekly meetings, and online refresher courses. All Vendor employees servicing Kiosk Drop-Off Sites

and/or Standard Mail-Back Services will have a training base similar to that of Service Technicians, with customized training as needed.

X. Vendor, Transporter, and Disposal Facility Information

Technician-Assisted Collection for Kiosk Drop-Off Sites and Take-Back Event Collection Services

A. Vendor for Technician-Assisted Collection Kiosk Drop-Off Sites and Take-Back Events

- Name: Stericycle Specialty Waste Solutions, Inc. ("Stericycle") will service Technician-Assisted
 Collection Kiosk Drop-Off Sites. Stericycle may also service Take-Back Events.
- Address: 2850 100th Court NE, Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Penalty Record (5 years): None

B. Carrier for Technician-Assisted Collection Kiosk Drop-Off Sites and Take-Back Events

- Name: United Parcel Service, Inc. may transport Unwanted Medicine from Technician-Assisted
 Collection Kiosk Drop-Off Sites to the Stericycle, Inc., Indianapolis, Indiana Facility or the Stericycle,
 Inc., Warren, Ohio Facility. United Parcel Service, Inc. may also transport Unwanted Medicine from
 Take-Back Events to the Stericycle, Inc., Indianapolis, Indiana Facility or the Stericycle, Inc., Warren,
 Ohio Facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA 30328
- Phone: (800) PICK-UPS
- Website: www.UPS.com/
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, UPS advises that "all material government investigation and enforcement activity is provided in our SEC filings at investors.ups.com"

C. Reverse Distributor Facility & Transporters for Technician-Assisted Collection Kiosk Drop-Off Sites and Take-Back Events

1. Reverse Distributor Facility

- Name: **Stericycle, Inc., Indianapolis, Indiana Facility** will receive Unwanted Medicine from United Parcel Service, Inc.
- Address: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: (317) 275-7530
- Website: www.stericycleenvironmental.com
- Type: DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA)
 Treatment, Storage, and/or Disposal Facility
- Penalty Record (5 years): See Appendix M

2. Transporter 1

- Name: **Heritage Transport** may transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Heritage Thermal Services Ohio.
- Address: 1626 Research Way, Indianapolis, IN 46231
- Phone: (317) 486-2973
- Website: http://www.heritage-enviro.com/
- Type: Hazardous Waste Transporter
- Penalty Record (5 years): None

3. Transporter 2

- Name: **Veolia Port Arthur** may be used to transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Veolia Port Arthur.
- Address: 7665 Texas Highway 73, Beaumont, TX 77705
- Phone: (409) 736-2821
- Website: www.veolianorthamerica.com
- Type: Hazardous Waste Transporter
- Penalty Record (5 years): See Appendix M

4. Transporter 3

- Name: Stericycle Specialty Waste Solutions, Inc. may transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to facilities listed in Section X.D or Section X.H.
- Address: 2850 100th Court NE, Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Type: Hazardous Waste Transporter
- Penalty Record (5 years): None

5. Transporter 4

- Name: **Tri-State Motor Transit Co.** may transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to facilities listed in Section X.D or Section X.H.
- Address: 8141 E. 7th St., Joplin, MO, 64801
- Phone: (877) 860-1600
- Website: https://tristatesecured.com/
- Type: Hazardous Waste Transporter
- US DOT No: 1007292, Status: Issued
- DOT Hazmat Permit No: US-1007292-MO-HMSP, Status: Issued
- Penalty Record (5 years): None

D. Disposal Facilities for Technician-Assisted Collection Kiosk Drop-Off Sites and Take-Back Events

1. Disposal Facility 1

- Name: **Heritage Thermal Services Ohio** may incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 1250 Saint George Street, East Liverpool, OH 43920
- Phone: (800) 545-7655
- Website: http://www.heritage-thermal.com/
- Type: Permitted Hazardous Waste Incinerator
- Penalty Record (5 years): See Appendix M

2. Disposal Facility 2

- Name: Veolia Port Arthur may incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 7665 Texas Highway 73, Beaumont, TX 77705
- Phone: (409) 736-2821
- Website: www.veolianorthamerica.com
- Type: Permitted Hazardous Waste Incinerator
- Penalty Record (5 years): See Appendix M

3. Disposal Facility 3

- Name: **Stericycle, Inc., Warren, Ohio Facility** may incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 1901 Pine Avenue, S.E., Warren, OH 44483
- Phone: (330) 393-0370
- Website: https://www.stericycle.com/service-locations/ohio/warren
- Type: Medical Waste Incinerator
- Penalty Record (5 years): None

4. Disposal Facility 4

- Name: Clean Harbors Aragonite may incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 3 Miles E 7 Miles N of Knolls, Wendover, UT 84083
- Phone: (435) 884-8900
- Website: <u>www.cleanharbors.com</u>
- Type: Permitted Hazardous Waste Incinerator
- Penalty Record (5 years): See Appendix M

Host-Assisted Collection Kiosk Drop-Off Sites

E. Vendors for Host-Assisted Collection Kiosk Drop-Off Sites

1. Vendor 1

- Name: Covanta Environmental Solutions, LLC may provide boxes and inner liners for Host-Assisted Collection Kiosk Drop-Off Sites.
- Address: 7326 E. Evans Road Suite B, Scottsdale, AZ 85620
- Phone: (855) 269-1750
- Website: <u>www.covantaes.com</u>
- Penalty Record (5 years): None

2. Vendor 2

- Name: Stericycle Specialty Waste Solutions, Inc. may provide boxes and inner liners for Host-Assisted Collection Kiosk Drop-Off Sites.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Penalty Record (5 years): None

F. Carrier for Host-Assisted Collection Kiosk Drop-Off Sites

- Name: United Parcel Service, Inc. may transport Unwanted Medicine from Host-Assisted Collection Kiosk Drop-Off Sites to the Covanta Manheim, Pennsylvania Facility. United Parcel Service, Inc. may also transport Unwanted Medicine from Host-Assisted Collection Kiosk Drop-Off Sites to the Stericycle, Inc., Indianapolis, Indiana Facility or the Stericycle, Inc., Warren, Ohio Facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA, 30328
- Phone: 800-PICK-UPSWebsite: www.UPS.com/
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, UPS advises that "all material government investigation and enforcement activity is provided in our SEC filings at investors.ups.com"

G. Reverse Distributor Facility & Transporter for Host-Assisted Collection Kiosk Drop-Off Sites

1. Reverse Distributor Facility 1

- Name: Covanta Manheim, Pennsylvania Facility may receive Unwanted Medicine from United Parcel Service, Inc.
- Address: 190 Shellyland Road, Manheim, PA 17545
- Phone: (717) 653-8882
- Website: www.covantaes.com
- Type: DEA Registered Collector and Reverse Distributor
- Penalty Record (5 years): None

2. Reverse Distributor Facility 2

- Name: **Stericycle, Inc., Indianapolis, Indiana Facility** may receive Unwanted Medicine from United Parcel Service. Inc.
- Address: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: (317) 275-7530
- Website: www.stericycleenvironmental.com
- Type: DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA)
 Treatment, Storage, and/or Disposal Facility
- Penalty Record (5 years): See Appendix M

3. Transporter 1

- Name: **Doncin Transport, Inc.** may transport Unwanted Medicine from the Covanta Manheim, Pennsylvania Facility to the Curtis Bay Energy, LP Medical Waste Incinerator.
- Address: 3478 Sunnyside Rd., Manheim, PA 17545
- Phone: (602) 344-4536
- Type: Contract Carrier
- Penalty Record (5 years): None

4. Transporter 2

- Name: Stericycle Specialty Waste Solutions, Inc. may transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to the Stericycle, Inc., Warren, Ohio Facility.
- Address: 2850 100th Court NE, Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Type: Hazardous Waste Transporter
- Penalty Record (5 years): None

5. Transporter 3

- Name: **Tri-State Motor Transit Co.** may transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to facilities listed in Section X.D or Section X.H.
- Address: 8141 E. 7th St., Joplin, MO, 64801
- Phone: (877) 860-1600
- Website: https://tristatesecured.com/
- Type: Hazardous Waste Transporter
- US DOT No: 1007292, Status: Issued
- DOT Hazmat Permit No: US-1007292-MO-HMSP, Status: Issued
- Penalty Record (5 years): None

H. Disposal Facilities for Host-Assisted Collection Kiosk Drop-Off Sites

1. Disposal Facility 1

- Name: Curtis Bay Energy, LP will incinerate Unwanted Medicine received from the Covanta Manheim, Pennsylvania Facility
- Address: 3200 Hawkins Point Road Baltimore, MD 21226
- Phone: (855) 228-1715
- Website: www.curtisbayenergy.com
- Type: Permitted Medical Waste Incinerator
- Penalty Record (5 years): See Appendix M

2. Disposal Facility 2

- Name: **Stericycle, Inc., Warren, Ohio Facility** may incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility or United Parcel Service, Inc.
- Address: 1901 Pine Avenue, S.E., Warren, OH 44483
- Phone: (330) 393-0370
- Website: https://www.stericycle.com/service-locations/ohio/warren
- Type: Medical Waste Incinerator
- Penalty Record (5 years): None

Standard Mail-Back Services

I. Vendors for Standard Mail-Back Packages

1. Vendor 1

- Name: Stericycle Specialty Waste Solutions, Inc. may provide Standard Mail-Back Packages.
- Address: 2850 100th Court NE, Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Penalty Record (5 years): None

2. Vendor 2

- Name: Covanta Environmental Solutions, LLC may provide Standard Mail-Back Packages.
- Address: 7326 E. Evans Road, Suite B, Scottsdale, AZ 85620
- Phone: (855) 269-1750
- Website: <u>www.covantaes.com</u>
- Penalty Record (5 years): None

J. Carrier for Standard Mail-Back Packages

- Name: United States Postal Service may ship Standard Mail-Back Packages to the Stericycle, Inc., Warren, Ohio facility. United States Postal Service may also ship Standard Mail-Back Packages to the Covanta Manheim, Pennsylvania Facility.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: <u>www.USPS.com/</u>
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, see <u>USPS SEC filings</u>

K. Reverse Distributor Facilities and Transporter for Standard Mail-Back Packages

1. Reverse Distributor Facility

- Name: Covanta Manheim, Pennsylvania Facility will receive Standard Mail-Back Packages from Covanta Environmental Solutions, LLC from United States Postal Service.
- Address: 190 Shellyland Road, Manheim, PA 17545
- Phone: (717) 653-8882
- Website: <u>www.covantaes.com</u>
- Type: DEA Registered Collector and Reverse Distributor
- Penalty Record (5 years): None

2. Transporter

- Name: Doncin Transport, Inc. will transport Standard Mail-Back Packages from the Covanta Manheim, Pennsylvania Facility to Covanta Lancaster and/or Covanta York.
- Address: 3478 Sunnyside Rd., Manheim, PA 17545
- Phone: (602) 344-4536
- Website:

http://www.truckdrivingcdljobs.com/in/Pennsylvania/Manheim/DONCIN%20TRANSPORT%20INC.php

- Type: Contract Carrier
- Penalty Record (5 years): None

⁷ Standard Mail-Back Packages distributed before Vendor moved the destruction of MED-Project Standard Mail-Back Packages to the Stericycle, Inc., Warren, Ohio facility are addressed to the Stericycle, Inc., Indianapolis, Indiana facility identified in Plan Section X.C.1 and delivered there by the United States Postal Service. Any such Standard Mail-Back Packages Residents return will be forwarded from the Stericycle, Inc., Indianapolis, Indiana facility to the Stericycle, Inc., Warren, Ohio facility for incineration via United Parcel Service. *See* 21 CFR § 1317.70(e)

L. Disposal Facilities for Standard Mail-Back Packages

1. Disposal Facility 1

- Name: Stericycle, Inc. Warren, Ohio will incinerate Standard Mail-Back Packages provided by Stericycle and received from United States Postal Service.
- Address: 1901 Pine Avenue, S.E., Warren, OH 44483
- Phone: (330) 393-0370
- Website: www.stericycle.com/service-locations/ohio/warren
- Type: Medical Waste Incinerator
- Penalty Record (5 years): None

2. Disposal Facility 2

- Name: Covanta Lancaster will incinerate Standard Mail-Back Packages provided by Covanta Environmental Solutions, LLC and received from the Covanta Manheim, Pennsylvania Facility.
- Address: 1911 River Road, Bainbridge, PA 17502
- Phone: (717) 397-9968
- Website: www.covanta.com
- Type: Municipal Waste Combustor
- Penalty Record (5 years): None

3. Disposal Facility 3

- Name: Covanta York will incinerate Standard Mail-Back Packages provided by Covanta Environmental Solutions, LLC and received from the Covanta Manheim, Pennsylvania Facility.
- Address: 2651 Blackbridge Road, York, PA 17406
- Phone: (717) 843-2902
- Website: www.covanta.com
- Type: Municipal Waste Combustor
- Penalty Record (5 years): None

Injector Mail-Back Services

M. Vendor for Injector Mail-Back Packages

- Name: PureWay Compliance Inc. will provide Injector Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy, TX 77450
- Phone: (877) 765-3030
- Website: http://pureway.com/
- Penalty Record (5 years): None

N. Carrier for Injector Mail-Back Packages

- Name: United States Postal Service will transport Injector Mail-Back Packages to a transfer facility.
 United States Postal Service may also transport Injector Mail-Back Packages to Curtis Bay Energy,
 LP Baltimore, Maryland.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: www.USPS.com/
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, see <u>USPS SEC filings</u>

O. Disposal Facilities for Injector Mail-Back Packages

- Name: Curtis Bay Energy, LP will incinerate Injector Mail-Back Packages received from United States Postal Service or a transfer facility.
- Address: 3200 Hawkins Point Road, Baltimore, MD 21226
- Phone: (855) 228-1715
- Website: www.curtisbayenergy.com
- Type: Permitted Medical Waste Incinerator
- Penalty Record (5 years) See Appendix M

Inhaler Mail-Back Services

P. Vendors for Inhaler Mail-Back Packages

1. Vendor 1

- Name: PureWay Compliance Inc. may provide Inhaler Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy, TX 77450
- Phone: (877) 765-3030
- Website: http://pureway.com/
- Penalty Record (5 years): None

2. Vendor 2

- Name: Stericycle Specialty Waste Solutions, Inc. may provide Inhaler Mail-Back Packages.
- Address: 2850 100th Court NE, Blaine, MN 55449
- Phone: (612) 285-9865
- Website: www.stericycleenvironmental.com
- Penalty Record (5 years): None

Q. Carriers for Inhaler Mail-Back Packages

1. Carrier 1

- Name: United Parcel Service, Inc. will transport Inhaler Mail-Back Packages provided by PureWay Compliance Inc. to a transfer facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA 30328
- Phone: (800) PICK-UPS
- Website: www.USPS.com/
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, UPS advises that "all material government investigation and enforcement activity is provided in our SEC filings at investors.ups.com"

2. Carrier 2

- Name: United States Postal Service will transport Inhaler Mail-Back Packages provided by Stericycle to the Stericycle, Inc. Warren, Ohio Facility.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: (202) 268-2000
- Website: www.USPS.com/
- Type: Common Carrier
- Penalty Record (5 years): For enforcement history, see USPS SEC filings

R. Transporter(s) for Inhaler Mail-Back Packages

1. Transporter 1

- Name: Lula Logistics Inc. may transport Inhaler Mail-Back Packages provided by PureWay
 Compliance Inc. and received from a transfer facility to the Covanta Huntsville, Inc. or Covanta
 Marion, Inc. Municipal Waste Combustors.
- Address: 8268 Nelson Ridge Ln, Las Vegas, NV 89178
- Phone: (352) 346-6219
- Email: https://www.lulalogisticsinc.com/
- Type: Contract Carrier
- Penalty Record (5 years): None

2. Transporter 2

- Name: GPB Logistics Inc. may transport Inhaler Mail-Back Packages provided by PureWay
 Compliance Inc. and received from a transfer facility to the Covanta Huntsville, Inc. or Covanta
 Marion, Inc. Municipal Waste Combustors.
- Address: 2115 W Farwell Ave #103, Chicago, IL 60645
- Phone: (773) 968-7210
- Website: <u>www.gpblogistics.com</u>
- Type: Contract Carrier
- Penalty Record (5 years): None

S. Disposal Facilities for Inhaler Mail-Back Packages

1. Disposal Facility 1

- Name: Covanta Huntsville, Inc. will incinerate Inhaler Mail-Back Packages provided by PureWay Compliance Inc. and received from a transfer facility.
- Address: 5251 Triana Blvd SW, Huntsville, AL 35805
- Phone: (256) 882-1019
- Website: https://www.covanta.com/Our-Facilities/Covanta-Huntsville
- Type: Municipal Waste Combustor
- Penalty Record (5 years): None

2. Disposal Facility 2

- Name: Covanta Marion, Inc. will incinerate Inhaler Mail-Back Packages provided by PureWay Compliance Inc. and received from a transfer facility.
- Address: 4850 Brook Lake Rd. NE, Brooks, OR 97305
- Phone: (503) 393-0890
- Website: https://www.covanta.com/Our-Facilities/Covanta-marion
- Type: Municipal Waste Combustor
- Penalty Record (5 years): None

3. Disposal Facility 3

- Name: **Stericycle, Inc. Warren, Ohio** will incinerate Inhaler Mail-Back Packages provided by Stericycle and received from the United States Postal Service.
- Address: 1901 Pine Avenue, S.E., Warren, OH 44483
- Phone: (330) 393-0370
- Website: www.stericycle.com/service-locations/ohio/warren
- Type: Medical Waste Incinerator
- Penalty Record (5 years): None

XI. Unwanted Medicine Educational and Outreach Programming

A. Overview

Per Ordinance § 4.116.060, MED-Project will perform public education and outreach to educate Residents about the collection and disposal of Unwanted Medicine from households.

B. Audiences

To effectively educate the public about the Program, MED-Project will develop a comprehensive communications campaign featuring both broad communications tactics as well as targeted outreach to audiences directly involved in the distribution of medicines to Residents on an annual basis. These audiences shall include:

- General public;
- Pharmacies, including education for dispensers of Covered Drugs;
- Retailers of Covered Drugs;
- Health care providers and their patients;
- Veterinary facilities and veterinary hospitals;
- Public health facilities: and/or
- Law enforcement agencies

The Program will include efforts to reach the varied cultural, linguistic, geographic, and age demographics, including through outreach to ethnic, community, and alternate-language media; outreach to community organizations serving a broad range of audiences; availability of alternate-language phone lines (Section XI.D.1); and availability of educational information through a broad range of media platforms.

C. Messages

MED-Project anticipates that messaging will:

- Educate Residents about the appropriate use, storage, and disposal of Unwanted Medicine;
- Educate Residents about available Mail-Back Services; and
- Provide Residents with information about available Kiosk Drop-Off Sites and Mail-Back Distribution Locations in their area that offer disposal of Unwanted Medicine.

Key points of emphasis might include:

- The importance of taking medicines as prescribed by your health care provider;
- The importance of adhering to and completing your provider-prescribed therapy;
- The importance of properly and securely storing medicines;
- The importance of promptly and properly disposing of Unwanted Medicine;
- How to find and use Kiosk Drop-Off Sites;
- How to properly dispose of Unwanted Medicine; and
- Privacy issues (removing personally identifiable information from labeled prescription containers).

D. Tools/Communications Channels

The Program will include a number of components designed to reach consumers and provide consistent access to timely and relevant information. MED-Project will provide a minimum of 50 copies of the educational brochure (Appendix N) in English and 25 copies in each of the other Required Language on an annual basis and upon request to LEAs, pharmacies, health care providers and systems, health associations, local government agencies, veterinarians, veterinary hospitals, and other community organizations within 60 days of provision of a list of these entities by the Director. MED-Project will provide a minimum of 50 copies of the educational brochure (Appendix N) in English and 25 copies in each of the other Required Languages on an annual basis and upon request to LEAs, pharmacies, health care providers and systems, health associations, local government agencies, veterinarians, veterinary hospitals, and other community organizations within 60 days of provision of a list of these entities by the Director. MED-Project will provide a log of when each stakeholder was provided with educational brochures in each annual report (see Section XV). MED-Project expects that the tools and communication channels will include the following.

1. Call Center

The Program will provide a Call Center for Residents to obtain information about Kiosk Drop-Off Sites and Mail-Back Distribution Locations, educational materials, and other aspects of the Program for the take-back of Unwanted Medicine from households. The Call Center will provide:

- Operator support in the Required Languages;
- Basic information about how the Program works, where to obtain more information (e.g., the MED-Project Website), and where to find Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations, if applicable, in the Resident's zip code or local area;
- Mail-Back Service request submission;
- Information directing callers with medical emergencies to call 911 and directing Residents with medication-related questions to contact their health care provider(s); and
- Text telephone services for Residents who are hearing impaired.

Please see Appendix O for a sample call script.

2. MED-Project Website

MED-Project has a mobile-friendly MED-Project Website with translations in the Required Languages. MED-Project expects information available to users will include pages to help Residents find locations of Kiosk Drop-Off Sites and Mail-Back Distribution Locations, educational materials, frequently asked questions and responses, and results of the most recent survey of Program awareness. When changes occur, the MED-Project Website will be updated within five (5) to ten (10) business days of the change to ensure the most current information is available.

- The Plan includes sample web pages for the MED-Project Website. <u>Appendix P</u> provides a proof of concept example for a possible MED-Project Website.
- The MED-Project Website will also include access to a public relations toolkit in a downloadable format (see Section XI.D.3) and contact information for Residents. A toolkit could include items such as a flyer/brochure (See Appendix N) and a frequently asked questions (FAQ). Translations of the brochure and FAQ will be available in the Required Languages.
- Community and government organizations and other public interest groups seeking materials to promote the Program will be encouraged to access these resources.

3. Materials

Educational materials about the Program and how to properly dispose of Unwanted Medicine, Pre-filled Injector Products, and inhalers will be available through the MED-Project Website and provided to the potential third-party partners and community organizations listed in Section XI.D and Kiosk Drop-Off Sites annually.

The Plan includes a sample of the information and educational brochure (<u>Appendix N</u>). Educational materials will be updated annually, as needed and will use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency.

MED-Project will provide Kiosk Drop-Off Sites, upon request, with signage and/or handout materials specifying the availability of Mail-Back Services for Pre-filled Injector Products and inhalers. *See* Appendices E, N, and O for samples of posters, web pages, brochures, and inserts regarding Mail-Back Services for Pre-filled Injector Products and inhalers.

4. Media Outreach

MED-Project expects that the Program will conduct public outreach through mediums such as traditional and social media, posting of educational signage, and at community events. Outreach efforts will encourage media outlets and third-party groups to download and use the toolkit. The following will support the Unwanted Medicine educational and outreach programming:

- See Appendix O for a call script with the toolkit including flyers in Appendix N and the sample MED-Project Website information included in Appendix P.
- Please see Appendix Q for a sample list of key media outlets.
- Please see Appendix R for a sample list of social media outlets.
- Please see Appendix S for a communication plan.

MED-Project expects to achieve a combined target reach of 50% at a 2+ frequency for the duration of one month, at least three times per year for years 2 through 4 of the Program. MED-Project intends to meet these requirements with a combination of digital media campaigns, print ads, and traditional broadcast media. The quantity and frequency will be confirmed as activities are completed.

E. Collaboration with County Officials and Community Organizations

MED-Project expects that the Program will work in collaboration with the County, as appropriate, to build on existing community outreach resources, such as local organizations, media lists, available public media outlets, etc.

The Program will perform the following activities:

- Briefing Materials Provided to Support Coordination with County Officials:
 - The Program will provide access to educational and outreach materials, including the sample brochure (see Appendix N), to relevant departments and officials.
- Outreach through Community Organizations:
 - The Program will engage relevant stakeholders and community organizations on up to a
 quarterly basis by providing selected community organizations identified in <u>Appendix B</u>
 with the toolkit included in <u>Appendix N</u>.

F. Disclaimer

The written and verbal educational materials and public outreach tools that are required by the Ordinance and disseminated under this Plan will include a disclaimer similar to the following: "This material has been provided for the purposes of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan."

XII. Survey

Per Ordinance § 4.116.060(a)(4), MED-Project will coordinate with other approved stewardship plans, if applicable, to conduct a biennial survey of Residents, pharmacists, veterinarians, and/or health professionals who interact with members of the community, according to requirements in the Ordinance.

Survey questions will be designed to measure, at a minimum, (1) percent awareness of the Programs, (2) whether drop-off sites and other collection methods are convenient and easy to use, and (3) knowledge and attitudes about risks of abuse, poisonings, and overdoses from prescription and nonprescription drugs used in the home. As required by the Ordinance § 4.116.060(a)(4), draft survey questions will be submitted to the Director for review and comment at least thirty (30) days prior to distribution. Results of the survey will be reported to the Director and made public on the MED-Project Website described under Section XI.D.2. The privacy of all survey respondents will be maintained.

The biennial survey will be conducted in the Required Languages and according to requirements outlined in the Ordinance.

XIII. Packaging

The Ordinance requires that a Plan consider "separating covered drugs from packaging to the extent possible to reduce transportation and disposal costs; and recycling of Drug packaging to the extent feasible." Ordinance § 4.116.040(h).

MED-Project has considered and evaluated options for the separation and recycling of drug packaging. Separating and recycling drug packaging collected under the Plan would require the management of separate waste streams at Kiosk Drop-Off Sites, including a waste stream for drug packaging and a waste stream for the drugs themselves.

While drug packaging is expected to constitute a significant amount of the waste incinerated under the Plan, MED-Project has concluded that separation of inner and/or outer packaging form Unwanted Medicine and/or recycling would raise three significant concerns:

- 1. Separating and recycling drug packaging could result in the disclosure of confidential patient information appearing on prescription drug packaging;
- 2. Separating and recycling drug packaging could increase the potential for releases and leakage of Unwanted Medicine; and
- Separating and recycling drug packaging could increase diversion risk by adding additional steps
 to the collection process and, because drug packaging is often used in drug counterfeiting, could
 be a diversion target itself.

For these reasons, the Plan does not provide for the separation and recycling of packaging from Unwanted Medicine.

MED-Project education and outreach materials instruct Residents to return Unwanted Medicine at a Kiosk Drop-Off Site or via Mail-Back Services, in its original container or in a sealed bag. These materials encourage Residents who transfer their Unwanted Medicine in a sealed bag to recycle all remaining packaging.

XIV. Compliance with Applicable Laws, Regulations, and Other Legal Requirements

The Ordinance requires that a Plan describe how all entities participating in the Program will "operate under" all applicable laws, regulations, and other legal requirements. Ordinance § 4.116.040(d). As described in more detail below, the Plan is designed such that all entities participating in the Program shall comply with all applicable laws, regulations, and other legal requirements.

A. DEA Controlled Substances Act and Implementing Regulations

On October 12, 2010, the United States Congress enacted the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act") as amendments to the Controlled Substances Act ("CSA"). The Disposal Act amended the CSA to allow for the expansion of entities to which users can deliver pharmaceutical controlled substances for disposal, subject to regulations to be promulgated. On September 9, 2014, the DEA adopted a rule entitled "Disposal of Controlled Substances" to implement the Disposal Act.

Under the DEA Rule, collection of controlled substances is limited to Schedule II, III, IV, or V controlled substances that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property. See DEA Rule §§ 1317.75(b) (Kiosk Drop-Off Sites)8; 1317.70(b) (Standard Mail-Back Services). Schedule I controlled substances, controlled substances that are not lawfully possessed as described above, and other illicit or dangerous substances will not be collected. Additionally, as these provisions of the DEA Rule limit collection of controlled substances to those lawfully possessed by an ultimate user or certain other persons, pharmacies are prohibited from disposing their own inventory or stock through the MED-Project Program. See also DEA Rule § 1317.05.

The DEA Rule provides that LEAs can continue to accept controlled substances for disposal. However, the DEA Rule also provides that pharmacies, reverse distributors, hospitals/clinics with on-site pharmacies, and certain other entities, can register with the DEA as "collectors" and become authorized at their discretion on a voluntary basis to accept controlled substances. The DEA Rule:

- Provides for the collection of controlled substances at Kiosk Drop-Off Sites at LEAs, pharmacies, and hospitals or clinics with on-site pharmacies:
- Provides for collection of controlled substances at Take-Back Events:
- Provides for the use of mail-back programs to collect controlled substances;
- Allows for the commingling of controlled and non-controlled substances;
- Establishes detailed collection, recordkeeping, security, and other measures for all approved collection methods; and
- Provides that all collected pharmaceutical products be destroyed so that the products are rendered non-retrievable.

The Plan is designed such that all entities that are part of the Program, including Vendor, are individually responsible to comply with their respective compliance obligations under the DEA Rule. Vendor will ensure that the collection, transportation, and disposal of Unwanted Medicine collected from Kiosk Drop-Off Sites and via Standard Mail-Back Services, including controlled substances, complies with all DEA requirements, including those in DEA Rule § 1317.

Controlled substances collected pursuant to the Plan may be commingled with non-controlled substances at Kiosk Drop-Off Sites and Take-Back Events, and through Standard Mail-Back Services per the DEA Rule.

⁸ For Kiosk Drop-Off Site collection, only certain substances "that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected." DEA Rule §1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Standard Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent's property. See DEA Rule §§ 1317.65(d); 1317.70(b).

See DEA Rule §§ 1317.75(b) (Kiosk Drop-Off Sites); 1317.65(d) (Take-Back Events); 1317.70(b) (Standard Mail-Back Services).

1. DEA Registration Modification

Pursuant to 21 C.F.R. § 1301.51(b), pharmacies may modify their registrations to become authorized collectors by submitting a written request to the DEA or online at www.DEAdiversion.usdoj.gov. This request must contain:

- The registrant's name, address, and registration number (as printed on the registration certificate);
- The collection methods the registrant intends to conduct; and
- A signature in accordance with DEA Rule § 1301.13(j).

See DEA Rule § 1301.51(b). MED-Project will consult with participating pharmacies, as requested, regarding how to modify their DEA registration to become authorized collectors.

B. United States Department of Transportation (DOT)

When preparing Unwanted Medicine for transport and transporting Unwanted Medicine, Vendor or the Host-Assisted Collection Kiosk Drop-Off Site will ensure compliance with the DOT HMR.

C. California State Board of Pharmacy

On June 8, 2017, the Board of Pharmacy adopted the Board of Pharmacy Regulations, Article 9.1 of Division 17 of Title 16 of the California Code of Regulations ("CCR"). Largely based on the DEA Rule, the Board of Pharmacy Regulations establish requirements applicable to pharmacies, hospitals/clinics with on-site pharmacies, distributors, and reverse distributors conducting certain drug take-back services. Among other things, the Board of Pharmacy Regulations provide:

- That California-licensed pharmacies and hospitals/clinics with on-site pharmacies must be in good standing with, and notify, the Board of Pharmacy to host a drug kiosk. See 16 CCR §§ 1776, 1776.1(i).
- That pharmacies must "know and adhere" to all applicable "federal, state, and local requirements governing the collection and destruction of dangerous drugs" when operating a drug take-back program. See 16 CCR § 1776.1(b).
- Drug kiosk placement and monitoring requirements. See 16 CCR §§ 1776.3(b)-(d).
- Drug kiosk inner liner, container, and signage requirements. See 16 CCR §§ 1776.3(f), (h), (m).
- Inner liner handling, storage, and destruction requirements for drug kiosks. *See, e.g.*, 16 CCR §§ 1776.3(h)-(j), 1776.5(a)-(c).
- Pharmacy and reverse distributor recordkeeping requirements. See 16 CCR §§ 1776.5(e)-(f), 1776.6.
- Pharmacy drug mail-back program requirements. See 16 CCR § 1776.2.

The Plan is designed such that all entities that are part of the Program, including Vendor, are individually responsible for complying with their respective compliance obligations under the Board of Pharmacy Regulations.

XV. Annual Report

An annual report will be provided to the Director within six months after the end of the first twelve-month period of operation and annually thereafter. Ordinance § 4.116.090(a). This report will be provided in the format required by the Ordinance.

For the reporting period, the report will include:

- A list of producers participating in the Program;
- The amount, by weight, of Unwanted Medicine collected, including the amount by weight from each collection method used, including Kiosk Drop-Off Sites and Mail-Back Services (using an average weight per package/container/envelope, as provided by Vendor);
- A list of Kiosk Drop-Off Sites and Mail-Back Distribution Locations;
- The number of mailers provided, by zip code;
- The dates and locations of Take-Back Events;
- Transporters, treatment, and disposal facilities used;
- Whether any safety or security problems occurred during collection, transportation, treatment, or disposal of Unwanted Medicine and, if so, what changes have or will be made to policies, procedures or tracking mechanisms to alleviate the problem and improve safety and security;
- A description of public education, outreach, and evaluation activities implemented, which will include a log of when each stakeholder was provided with educational brochures;
- A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- A summary of the Program goals, the degree of success meeting these goals in the past year, and how these goals will be achieved in the next year if they were not met;
- Communications plan analytics; and
- The Program's total expenditures.

Appendix A

MED-Project Participants

The list of participating Producers in MED-Project's Program in the County is provided to the County to satisfy Ordinance requirements. The below is a subset of the information provided on April 12, 2019.

Parent Company	Company Name	Address	City	State	Zip	Country
3M Corporation	3M Drug Delivery Systems	3M Center 275-5W-06	Saint Paul	MN	55144	United States
3M Corporation	3M Drug Delivery Systems	3M Center, 275-3E-02	St. Paul	MN	55144	United States
3M Corporation	3M ESPE	3M Center 275-5W-06	Saint Paul	MN	55144	United States
3M Corporation	3M Health Care	3M Center 275-5W-06	Saint Paul	MN	55144	United States
3M Corporation	3M Personal Care	3M Center 275-5W-06	Saint Paul	MN	55144	United States
AbbVie Inc.	AbbVie Inc.	1 North Waukegan Road	North Chicago	IL	60064	United States
AbbVie Inc.	Pharmacyclics, subsidiary of AbbVie Inc.	999 East Arques Avenue	Sunnyvale	CA	94085	United States
ACADIA Pharmaceuticals Inc.	ACADIA Pharmaceuticals Inc.	3611 Valley Centre Drive, Suite 300	San Diego	CA	92130	United States
Accord Healthcare Inc.	Accord Healthcare Inc.	1009 Slater Road, Suite 210-B	Durham	NC	27703	United States
Acorda Therapeutics, Inc.	Acorda Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
Acorda Therapeutics, Inc.	Acorda Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
Acorda Therapeutics, Inc.	Civitas Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
ACP Nimble Buyer, Inc.	ACP Nimble Buyer, Inc.	111 Coolidge St.	South Plainfield	NJ	07080	United States
Aegerion Pharmaceuticals, Inc.	Aegerion Pharmaceuticals, Inc.	One Main Street, Ste. 800	Cambridge	MA	02142	United States
Afaxys Inc.	Afaxys Inc.	PO Box 20639	Charleston	sc	29413	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Afaxys Inc.	Afaxys Pharmaceuticals (a division of Afaxys Inc.)	PO Box 20639	Charleston	SC	29413	United States
Ajanta Pharma USA Inc.	Ajanta Pharma USA Inc	440 US Highway 22 E., STE 150	Bridgewater	NJ	08807	United States
Akorn, Inc.	Akorn, Inc.	1925 West Field Court, Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Advanced Vision Research Inc. d.b.a. Akorn Consumer Health	C/O Akorn, Inc., 1925 West Field Court, Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Akorn Animal Health, Inc.	C/O Akorn, Inc, 1925 West Field Court, Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Clover Pharmaceuticals Corp.	C/O Akorn, Inc., 1925 West Field Court, Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Hi-Tech Pharmacal Co., Inc.	369 Bayview Avenue	Amityville	NY	11701	United States
Akorn, Inc.	Oak Pharmaceuticals, Inc.	C/O Akorn, Inc., 1925 West Field Court, Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Olta Pharmaceuticals Corp.	C/O Akorn, Inc., 1925 West Field Court Suite 300	Lake Forest	IL	60045	United States
Akorn, Inc.	Versapharm, Incorporated	C/O Akorn, Inc., 1925 West Field Court,Suite 300	Lake Forest	IL	60045	United States
Akrimax Pharmaceuticals, LLC	Akrimax Pharmaceuticals, LLC	11 Commerce Drive, First Floor	Cranford	NJ	07016	United States

Parent Company	Company Name	Address	City	State	Zip	Country
AKRON COATING & ADHESIVES	AKRON COATING & ADHESIVES	367 Stanton Ave	Akron	ОН	44301-1468	United States
Alembic Pharmaceuticals Inc.	Alembic Pharmaceuticals	750 Highway 202, Suite 410	Bridgewater	NJ	08807	United States
Allergan, Inc.	Allergan, Inc.	2525 Dupont Dr	Irvine	СА	92612-1599	United States
Allergan, Inc.	Actavis Pharma, Inc. (only for labeler code 52544)	400 Interpace Pkwy Bldg A	Parsippany	NJ	07054	United States
Allergan, Inc.	Allergan Sales, LLC	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Allergan USA, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Aptalis Pharma US, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Durata Therapeutics US Limited	c/o Durata Therapeautics, Inc., 200 S. Wacker Drive, Suite 2550	Chicago	IL	60606	United States
Allergan, Inc.	Forest Laboratories, LLC	Corporation Trust Centre, 1209 Orange St	Wilmington New Castle	DE	19801	United States
Allergan, Inc.	Pacific Pharma, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Warner Chilcott (US), LLC	5 Giralda Farms	Madison	NJ	07940- 1027	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Allergan, Inc.	Watson Laboratories, Inc. (only for labeler code 52544)	400 Interpace Pkwy Bldg A	Parsippany	ИЛ	07054	United States
Alva-Amco Pharmacal Companies, Inc.	Alva-Amco Pharmacal Companies, Inc.	7711 N Merrimac Avenue	Niles	IL	60714- 3423	United States
Alvogen Pharma US, Inc.	Alvogen Pharma US, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Almatica Pharma, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Alvogen, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	County Line Pharmaceuticals LLC	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Norwich Pharmaceuticals, Inc.	6829 State Highway 12	Norwich	NY	13815	United States
AMAG Pharmaceuticals, Inc.	AMAG Pharmaceuticals, Inc.	1100 Winter Street	Waltham	MA	02451	United States
AMAG Pharmaceuticals, Inc.	AMAG Pharma USA, Inc.	1100 Winter Street, Suite 3000	Waltham	МА	02451	United States
Amarin Pharma, Inc.	Amarin Pharma, Inc.	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Corp	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Corp. PLC	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Pharmaceuticals Ireland Ltd.	1430 Route 206	Bedminster	ИЛ	07921	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Amerisource Health Services, LLC DBA: American Health Packaging	Amerisource Health Services, LLC DBA: American Health Packaging	2550-A John Glenn Avenue	Columbus	ОН	43217	United States
Amgen Inc.	Amgen Inc.	One Amgen Center Drive	Thousand Oaks	CA	91320	United States
Amgen Inc.	Amgen USA	One Amgen Center Drive	Thousand Oaks	CA	91320	United States
Amgen Inc.	Immunex Corporation	One Amgen Center Drive	Thousand Oaks	CA	91320	United States
Amgen Inc.	Onyx Pharmaceuticals	249 N. Grand Avenue	South San Francisco	CA	94080	United States
Amneal Pharmaceuticals LLC	Amneal Pharmaceuticals LLC	400 Crossing Blvd Third Floor	Bridgewater	NJ	08807	United States
Amneal Pharmaceuticals LLC	Amedra Laboratories LLC	2 Walnut Grove Drive	Horsham	PA	19044-2219	United States
Amneal Pharmaceuticals LLC	CorePharma, LLC	215 Wood Avenue	Middlesex	NJ	08846	United States
Amneal Pharmaceuticals LLC	Gemini Laboratories, LLC	Tony Hodges, 400 Crossing Blvd Third Floor	Bridgewater	NJ	08807	United States
Amneal Pharmaceuticals LLC	Impax Laboratories, Inc.	400 Crossing Boulevard, Third Floor	Bridgewater	NJ	08807	United States
Amneal Pharmaceuticals LLC	Lineage Therapeutics Inc.	2 Walnut Grove	Horsham	PA	19044	United States
Amphastar Pharmaceuticals, Inc.	Amphastar Pharmaceuticals, Inc.	11570 Sixth Street	Rancho Cucamonga	СА	91730	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Amphastar Pharmaceuticals, Inc.	Armstrong Pharmaceuticals, Inc.	25 John Road	Canton	МА	02021	United States
Amphastar Pharmaceuticals, Inc.	International Medication Systems, LTD	1886 Santa Anita Ave	South El Monte	СА	91733	United States
Amring Pharmaceuticals Inc.	Amring Pharmaceuticals Inc.	1235 Westlakes Drive, Suite 205	Berwyn	PA	19312	United States
Apotex Holdings, Inc.	ApoPharma USA, Inc.	2400 N. Commerce Parkway, Suite 400	Weston	FL	33326	United States
Apotex Holdings, Inc.	Apotex Corp.	2400 N. Commerce Parkway, Suite 400	Weston	FL	33326	United States
Apotex Holdings, Inc.	Aveva Drug Delivery Systems, Inc.	2400 N. Commerce Parkway, Suite 400	Weston	FL	33326	United States
Aptevo BioTherapeutics LLC	Aptevo BioTherapeutics LLC	920 Cassatt Road	Berwyn	PA	19312	United States
Aqua Pharmaceuticals an Almirall Company	Aqua Pharmaceuticals an Almirall Company	707 Eagleview Blvd., Suite 200	Exton	PA	19341	United States
Aratana Therapeutics Inc	Aratana Therapeutics Inc	11400 Tomahawk Creek Parkway Suite 340	Leawood	Kansas	66211	United States
Arbor Pharmaceuticals, Inc.	Arbor Pharmaceuticals, Inc.	6 Concourse Parkway, Suite 1800	Atlanta	GA	30328	United States
Arbor Pharmaceuticals, Inc.	Wilshire Pharmaceuticals	6 Concourse Parkway, Suite 1800	Atlanta	GA	30328	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Ascend Laboratories, LLC	Ascend Laboratories, LLC	339 Jefferson Rd	Parsippany	NJ	07054- 3707	United States
Ascend Therapeutics US, LLC	Ascend Therapeutics US, LLC	607 Herndon Parkway, Suite 110	Herndon	VA	20170	United States
Assertio Therapeutics, Inc.	Assertio Therapeutics, Inc.	100 South Saunders Rd, Suite 300	Lake Forest	IL	60045- 2508	United States
Astellas Pharma US, Inc.	Astellas Pharma US, Inc.	1 Astellas Way	Northbrook	IL	60062	United States
AstraZeneca Pharmaceuticals LP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike, PO Box 15437	Wilmington	DE	19850- 5437	United States
AstraZeneca Pharmaceuticals LP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike, PO Box 15437	Wilmington	DE	19850- 5437	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma USA, Inc	279 Princeton Hightstown Road	East Windsor	NJ	08520- 1401	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma Limited	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma USA Incorporated	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroHealth, LLC	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroLife Pharma LLC	2400 Rt 130	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroMedics Pharma, LLC	6 Wheeling Road	Dayton	NJ	08810	United States
B.F. Ascher & Co., Inc.	B.F. Ascher & Co., Inc.	15501 W. 109th St.	Lenexa	KS	66219	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Bausch Health Companies	Bausch Health Companies	400 Somerset Corporate Blvd	Bridgewater	NJ	08807	United States
Bausch Health Companies	Bausch + Lomb	1400 N. Goodman St.	Rochester	NY	14609	United States
Bausch Health Companies	Salix	400 Somerset Corporate Blvd	Bridgewater	NJ	08807	United States
Baxter Healthcare Corporation	Baxter Healthcare Corporation	One Baxter Parkway	Deerfield	IL	60015	United States
Bayer HealthCare LLC	Bayer HealthCare LLC	100 Bayer Boulevard	Whippany	NJ	07981-0915	United States
Bayer HealthCare LLC	Bayer Consumer Care Holdings LLC	100 Bayer Blvd	Whippany	NJ	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Animal Health Inc.	12707 Shawnee Mission Parkway	Shawnee	KS	66216	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals Inc.	100 Bayer Blvd	Whippany	NJ	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals LLC	800 Dwight Way	Berkeley	CA	94710	United States
Bayer HealthCare LLC	MSD Consumer Care Inc.	100 Bayer Boulevard	Whippany	NJ	07981-0915	United States
Beach Products, Inc.	Pharmaceutical Associates, Inc.	3010 W de Leon St	Tampa	FL	33609	United States
Beach Products, Inc.	Beach Pharmaceuticals	3010 W. De Leon Street	Tampa	FL	33609	United States
Beach Products, Inc.	Pharmaceutical Associates, Inc.	3010 W. De Leon Street	Tampa	FL	33609	United States

Parent Company	Company Name	Address	City	State	Zip	Country
BestCo, Inc.	BestCo, Inc.	288 Mazeppa Road	Mooresville	NC	28027	United States
Biogen Inc.	Biogen Inc.	225 Binney Street	Cambridge	МА	02142	United States
BioMarin Pharmaceutical Inc.	BioMarin Pharmaceutical	105 Digital Drive	Novato	CA	94949	United States
Bionpharma Inc.	Bionpharma Inc.	600 Alexander Road, Suite 2- 4B	Princeton	NJ	08540	United States
Bionpharma Inc.	Banner Life Sciences LLC	600 Alexander Rd Ste 2-4B	Princeton	NJ	08540- 6013	United States
Blistex Inc.	Blistex Inc.	1800 Swift Drive	Oak Brook	IL	60523	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim USA, Inc.	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Animal Health Division	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Fremont, Inc.	6701 Kaiser Drive	Fremont	CA	94555	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Vetmedica, Inc.	2612 Belt Highway	St. Joseph	МО	64506	United States
Boehringer Ingelheim USA, Inc.	Merial Barceloneta, LLC	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Boehringer Ingelheim USA, Inc.	Merial Select, Inc.	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Boehringer Ingelheim USA, Inc.	Merial, Inc.	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States
Boehringer Ingelheim USA, Inc.	Newport Laboratories, Inc.	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Bristol-Myers Squibb Company	Bristol-Myers Squibb Company	P.O. Box 4500	Princeton	NJ	08543- 4500	United States
Bristol-Myers Squibb Company	Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership	Route 206 & Province Line Road	Princeton	NJ	08540- 4000	United States
Bristol-Myers Squibb Company	E.R. Squibb & Sons, LLC	P.O. Box 4500	Princeton	NJ	08543- 4500	United States
Bristol-Myers Squibb Company	Medarex, LLC	707 State Road	Princeton	NJ	08540- 1437	United States
Bristol-Myers Squibb Company	ZymoGenetics, Inc.	1201 Eastlake Ave E	Seattle	WA	98102	United States
Celgene Corporation	Celgene Corporation	86 Morris Avenue	Summit	NJ	07901	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	1255 Crescent Green Drive, Suite 600	Cary	NC	27518	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Chiesi USA	1255 Crescent Green Drive, Ste 250	Cary	NC	27518	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Cornerstone Therapeutics Inc.	1255 Crescent Green Drive, Ste 250	Cary	NC	27518	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Church & Dwight Company, Inc.	Church & Dwight Company, Inc.	469 N Harrison St	Princeton	NJ	08540- 3597	United States
Clarion Brands LLC	Clarion Brands LLC	27070 Miles Road, Suite A	Solon	ОН	44139	United States
Clovis Oncology, Inc.	Clovis Oncology, Inc.	5500 Flatiron Parkway	Boulder	СО	80301	United States
Colgate-Palmolive Company	Colgate-Palmolive Company	300 Park Avenue	New York	NY	10022	United States
Colgate-Palmolive Company	Colgate Oral Pharmaceuticals, Inc.	300 Park Avenue	New York	NY	10022	United States
Concordia Pharmaceuticals Inc.	Concordia Pharmaceuticals Inc.	5 Canewood Industrial Park	Canewood	St. Michael	BB11005	Barbados
CooperSurgical, Inc.	CooperSurgical, Inc.	95 Corporate Drive	Trumbull	СТ	06611	United States
Corcept Therapeutics	Corcept Therapeutics	149 Commonwealth Drive	Menlo Park	CA	94025	United States
CutisPharma, Inc.	CutisPharma, Inc.	841 Woburn Street	Wilmington	MA	01887-3414	United States
Daiichi Sankyo, Inc.	Daiichi Sankyo, Inc.	211 Mt. Airy Rd.	Basking Ridge	NJ	07920	United States
Daiichi Sankyo, Inc.	American Regent, Inc.	One Luitpold Drive	Shirley	NY	11967	United States
Davion Inc.	Davion Inc.	2 Progress Road	North Brunswick	NJ	08902	United States
Dechra Veterinary Products North America	Dechra Veterinary Products North America	7015 College Blvd, Ste 525	Leawood	KS	66211-1551	United States
Dechra Veterinary Products North America	Putney, Inc.	7015 College Blvd, Unit 525	Overland Park	KS	66211	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories, Inc	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories Louisiana, LLC	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories Tennessee, LLC	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Promius Pharma, LLC	107 College Road East	Princeton	NJ	08540	United States
DSE Healthcare Solutions, LLC	DSE Healthcare Solutions, LLC	105 Fieldcrest Avenue, Suite 502A	Edison	NJ	08837	United States
DSE Healthcare Solutions, LLC	Numark Brands, Inc.	105 Fieldcrest Avenue, Suite 502A	Edison	NJ	08837	United States
Duchesnay USA, Inc.	Duchesnay USA, Inc.	919 Conestoga Road, Building I, Suite 203	Rosemont	PA	19010	United States
Duchesnay USA, Inc.	Analog Pharma, Inc.	919 Conestoga Road, Building I, Suite 203	Rosemont	PA	19010	United States
Duchesnay USA, Inc.	Duchesnay Inc.	950 Boulevard Michele- Bohec	Blainville	Quebec	J7C 5E2	Canada
Duchesnay USA, Inc.	Medunik USA, Inc.	919 Conestoga Road, Building I, Suite 203	Rosemont	PA	19010	United States
e5 Pharma, LLC	e5 Pharma, LLC	225 Mizner Boulevard, Ste 770	Boca Raton	FL	33432	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Edenbridge Pharmaceuticals, LLC	Edenbridge Pharmaceuticals, LLC	169 Lackawanna Avenue, Suite 110	Parsippany	NJ	07054	United States
Eisai, Inc.	Eisai, Inc.	100 Tice Blvd	Wood Cliff Lake	NJ	07677	United States
Eli Lilly and Company	Eli Lilly and Company	Lilly Corporate Center	Indianapolis	IN	46285	United States
Eli Lilly and Company	Elanco US Inc.	2500 Innovation Way N	Greenfield	IN	46140-9163	United States
EMD Serono, Inc.	EMD Serono, Inc.	One Technology Place	Rockland	MA	02370	United States
Endo Pharmaceuticals Inc.	Endo Pharmaceuticals Inc.	1400 Atwater Drive	Malvern	PA	19355	United States
Endo Pharmaceuticals Inc.	Anchen Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	9601 Jeronimo Road	Irvine	СА	92618- 2025	United States
Endo Pharmaceuticals Inc.	Auxilium Pharmaceuticals, Inc.	640 Lee Road	Chesterbrook	PA	19087	United States
Endo Pharmaceuticals Inc.	BOCA Pharmacals, Inc.	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	DAVA Pharmaceuticals, Inc.	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Generics Bidco I, LLC (d/b/a Par Pharmaceutical)	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Generics Bidco II, LLC (d/b/a Par Pharmaceutical)	3241 & 3700 Woodpark Blvd	Charlotte	NC	28206	United States
Endo Pharmaceuticals Inc.	Innoteq, Inc. (d/b/a Par Pharmaceutical)	555 Lordship Blvd.	Stratford	СТ	06615	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Endo Pharmaceuticals Inc.	Par Pharmaceutical Companies, Inc.	One Ram Ridge Rd	Chestnut Ridge	NY	10977	United States
Endo Pharmaceuticals Inc.	Par Pharmaceutical, Inc.	300 Tice Boulevard	Woodcliff Lake	NJ	07677	United States
Endo Pharmaceuticals Inc.	Par Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	One Ram Ridge Rd	Chestnut Ridge	NY	10977	United States
Endo Pharmaceuticals Inc.	Par Sterile Products, LLC (d/b/a Par Pharmaceutical)	970 Parkdale Road	Rochester	МІ	48307	United States
Endo Pharmaceuticals Inc.	Quartz Specialty Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	130 Vintage Ave	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	120 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	150 Vintage Drive	Huntsville	AL	35811	United States
Exelixis, Inc.	Exelixis, Inc.	1851 Harbor Bay Parkway	Alameda	CA	94502	United States
Exelixis, Inc.	Exelixis US, LLC	210 E Grand Ave	South San Francisco	CA	94080-4811	United States
Ferring Pharmaceuticals Inc.	Ferring Pharmaceuticals Inc.	100 Interpace Parkway	Parsippany	NJ	07054	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Foundation Consumer Healthcare, LLC	Foundation Consumer Healthcare, LLC	1190 Omega Drive	Pittsburgh	PA	15205	United States
Fresenius Kabi USA, LLC	Fresenius Kabi USA, LLC	Three Corporate Drive	Lake Zurich	IL	60047	United States
Galderma Laboratories, L.P.	Galderma Laboratories, L.P.	14501 North Freeway	Fort Worth	TX	76177	United States
Garcoa Laboratories, Inc.	Garcoa Laboratories	26135 Mureau Road	Calabasas	CA	91302	United States
Genus Lifesciences Inc.	Genus Lifesciences Inc.	514 North 12th Street	Allentown	PA	18102	United States
Gilead Sciences, Inc.	Gilead Sciences, Inc.	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Asegua Therapeutics LLC	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences Limited	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences, Inc.	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences, LLC	333 Lakeside Drive	Foster City	CA	94404	United States
GlaxoSmithKline, LLC	GlaxoSmithKline, LLC	5 Crescent Drive	Philadelphia	PA	19112	United States
GlaxoSmithKline, LLC	GlaxoSmithKline Consumer Healthcare LP	184 Liberty Corner Road	Warren	NJ	07059	United States
GlaxoSmithKline, LLC	GlaxoSmithKline Holdings (US) LLC	5 Crescent Drive	Philadelphia	PA	19112	United States
GlaxoSmithKline, LLC	Novartis Consumer Health, Inc.	200 Kimball Drive	Parsippany	NJ	07054	United States

Parent Company	Company Name	Address	City	State	Zip	Country
GlaxoSmithKline, LLC	Stiefel Laboratories, Inc.	20 TW Alexander Dr, PO Box 14910	Research Triangle Park	NC	27709	United States
GlaxoSmithKline, LLC	ViiV Healthcare Company	5 Moore Drive	RTP	NC	27709	United States
Glenmark Pharmaceuticals Inc., USA	Glenmark Pharmaceuticals Inc., USA	750 Corporate Drive	Mahwah	NJ	07430	United States
Grifols Shared Services North America Inc.	Grifols Biologicals LLC	5555 Valley Blvd.	Los Angeles	CA	90032	United States
Grifols Shared Services North America Inc.	Grifols Therapeutics LLC	8368 US 70 Business Hwy West	Clayton	NC	27520	United States
Grifols Shared Services North America Inc.	Instituto Grifols S.A.	Poligono Industrial Levante, C Can Guasc, 2	Parets Del Valles	Barcelo na	08150	Spain
Grifols Shared Services North America Inc.	Laboratorios Grifols S.A.	Calle Logistica 2, Poligono Industrial Z	Parets del Valles	Barcelo na	08150	Spain
Grifols Shared Services North America Inc.	Talecris Biotherapeutics, Inc.	2410 Lillyvale Avenue	Los Angeles	CA	90032	United States
Harris Pharmaceutical, Inc.	Harris Pharmaceutical, Inc.	9090 Park Royal Drive	Ft. Myers	FL	33908	United States
Heritage Pharmaceuticals Inc.	Heritage Pharmaceuticals Inc.	One Tower Center, Suite 1700	East Brunswick	NJ	08816	United States
Hikma Pharmaceuticals, PLC	Hikma Pharmaceuticals, PLC	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom

Parent Company	Company Name	Address	City	State	Zip	Country
Hikma Pharmaceuticals, PLC	Hikma Algeria	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Algeria - Manufacturing Plant	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Asia Pacific	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Austria	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Bahrain	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Belgium	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Egypt - 6th October	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Egypt - Badr City	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Egypt - Beni Suef	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Egypt - Head Office	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Germany - Hikma Pharma GmbH	Hikma Pharma Gmbh, Lochhamer StrBe 13	82152 Martinsried			Germany

Parent Company	Company Name	Address	City	State	Zip	Country
Hikma Pharmaceuticals, PLC	Hikma Germany - Thymoorgan	Thymoorgan Pharmazie GmbH, Schiffgraben 23	D-38690 Goslar			Germany
Hikma Pharmaceuticals, PLC	Hikma Italy	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Jordan - Arabic Medical Containers LLC	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Jordan - Headquarters	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Jordan - International Pharma. Research Ctr LLC	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Jordan - Jordan Souq	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Jordan - Salt	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Kuwait	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Lebanon	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma MENA Building	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Morocco	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom

Parent Company	Company Name	Address	City	State	Zip	Country
Hikma Pharmaceuticals, PLC	Hikma Oman	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Pharmaceutcals USA, Inc.—Non-Injectables Manufacturing Facility	1809 Wilson Rd	Columbus	ОН	43228- 8601	United States
Hikma Pharmaceuticals, PLC	Hikma Pharmaceuticals USA, Inc. Headquarters	246 Industrial Way W	Eatontown	NJ	07724	United States
Hikma Pharmaceuticals, PLC	Hikma Pharmaceuticals USA, Inc.—Distribution Warehouse	4750 Pleasant Hill Rd	Memphis	TN	38118-7809	United States
Hikma Pharmaceuticals, PLC	Hikma Pharmaceuticals USA, Inc.—Injectable Manufacturing Facility	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
Hikma Pharmaceuticals, PLC	Hikma Pharmaceuticals USA, Inc.—Research & Development	300 Northfield Rd	Bedford	ОН	44146- 4650	United States
Hikma Pharmaceuticals, PLC	Hikma Portugal	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Qatar	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Saudi Arabia	Al Jazeerah Pharmaceutical Industries, P.O. Box 106229	11666 Riyadh			Saudi Arabia
Hikma Pharmaceuticals, PLC	Hikma Slovakia	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom

Parent Company	Company Name	Address	City	State	Zip	Country
Hikma Pharmaceuticals, PLC	Hikma Sudan - Pharma Ixir	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Sudan - Pharmaland	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Sudan - Savanna	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Tunisia - Ibn Al Bitar	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Tunisia - Medicef	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Hikma Pharmaceuticals, PLC	Hikma Yemen	1 New Burlington Place, Mayfair	London		W1S 2HR	United Kingdom
Horizon Pharma plc.		150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Orphan LLC	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Pharma Rheumatology LLC (formerly known as Crealta Pharmaceuticals LLC)	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Pharma USA, Inc.	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Therapeutics, Inc.	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	HZNP USA, Inc.	150 Saunders Rd	Lake Forest	IL	60045- 2509	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Incyte Corporation	Incyte Corporation	Attn: Incyte Corporation, P.O Box 42405	Indianapolis	IN	46241	United States
Indivior Inc	Indivior Inc	10710 Midlothian Turnpike, Suite 430	Richmond	VA	23235	United States
Ingenus Pharmaceuticals, LLC	Ingenus Pharmaceuticals, LLC	4190 Millenia Blvd.	Orlando	FL	32839	United States
Intergel Pharmaceuticals Inc.	International Vitamin Corporation	500 Halls Mill Rd	Freehold	NJ	07728-8811	United States
Invagen Pharmaceuticals, Inc.	Cipla USA, Inc.	7 Oser Avenue	Hauppauge	NY	11788	United States
Invagen Pharmaceuticals, Inc.	Cipla Limited	Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg	Lower Parel, Mumbai		400013	India
Invagen Pharmaceuticals, Inc.	Cipla USA, Inc.	1560 Sawgrass Corporate Parkway, STE 130	Sunrise	FL	33323	United States
Invagen Pharmaceuticals, Inc.	Exelan Pharmaceuticals, Inc.	242 S Culver St	Lawrenceville	GA	30046	United States
Ipsen Biopharmaceuticals, Inc	Ipsen Biopharmaceuticals, Inc	106 Allen Road	Basking Ridge	NJ	07920	United States
Jacobus Pharmaceutical Company, Inc.	Jacobus Pharmaceutical Company, Inc.	37 Cleveland Ln PO Box 5290	Princeton	NJ	08540- 3090	United States
Jazz Pharmaceuticals, plc	Jazz Pharmaceuticals, Inc.	3180 Porter Drive	Palo Alto	СА	94304	United States
Jazz Pharmaceuticals, plc	Jazz Pharmaceuticals, International Division	Wing B, Building 5700, Spires House, John Smith Drive	Oxford Business Park South	Oxford	OX4 2RW	United Kingdom

Parent Company	Company Name	Address	City	State	Zip	Country
Johnson & Johnson	Johnson & Johnson	One Johnson & Johnson Plaza, WH-7113	New Brunswick	NJ	08933	United States
Johnson & Johnson	Actelion	One Johnson & Johnson Plaza, WH-7113	New Brunswick	NJ	08933	United States
Johnson & Johnson	Janssen Biotech, Inc.	800/850 Ridgeview Drive	Horsham	PA	19044	United States
Johnson & Johnson	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road	Titusville	NJ	08560	United States
Johnson & Johnson	Janssen Products, LP	800/850 Ridgeview Dr.	Horsham	PA	19044	United States
Johnson & Johnson	Johnson & Johnson Consumer, Inc.	199 Grandview Road	Skillman	NJ	08558	United States
Johnson & Johnson	Johnson & Johnson Surgical Vision Inc	One Johnson & Johnson Plaza, WH-7113	New Brunswick	NJ	08933	United States
Johnson & Johnson	McNeil Consumer Healthcare Latin America LLC	7050 Camp Hill Road	Fort Washington	PA	19034	United States
Johnson & Johnson	McNeil Consumer Pharmaceuticals Co.	7050 Camp Hill Rd	Fort Washington	PA	19034- 2299	United States
Johnson & Johnson	McNeil Healthcare LLC	Road 183 KM 19.8	Barrio Montones	Las Piedras	00771	Puerto Rico
Johnson & Johnson	McNeil MMP, LLC	One Johnson & Johnson Plaza	New Brunswick	NJ	08933	United States
Johnson & Johnson	McNeil Nutritionals LLC	7050 Camp Hill Road	Fort Washington	РА	19034	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Johnson & Johnson	McNeil-PPC, Inc.					
Johnson & Johnson	Ortho-McNeil Finance LLC	6018 Bowendale Avenue	Jacksonville	FL	32216- 0995	United States
Johnson & Johnson	Patriot Pharmaceuticals, LLC	200 Tournament Drive	Horsham	PA	19044	United States
Jubilant Cadista Pharmaceuticals Inc.		207 Kiley Drive	Salisbury	MD	21801	United States
Kadmon Corporation, LLC	Kadmon Corporation, LLC	119 Commonwealth Dr	Warrendale	PA	15086- 7503	United States
Kadmon Corporation, LLC	Kadmon Pharmaceuticals, LLC	1450 East 29th Street, 5th Floor	New York	NY	10016	United States
Kaleo Inc.	Kaleo Inc.	111 Virginia Street Suite 300	Richmond	VA	23219	United States
Kowa Pharmaceuticals America, Inc.	Kowa Pharmaceuticals America, Inc.	530 Industrial Park Blvd.	Montgomery	AL	36117	United States
Kyowa Kirin, Inc.	Kyowa Kirin, Inc.	135 Route 202-206, Suite 6	Bedminster	NJ	07921	United States
L. Perrigo Company	L. Perrigo Company	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Athena Neurosciences, LLC	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Cobrek Pharmaceuticals, Inc.	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Elan Pharmaceuticals, LLC	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Paddock Laboratories, LLC	3940 Quebec Ave	Minneapolis	MN	55427	United States

Parent Company	Company Name	Address	City	State	Zip	Country
L. Perrigo Company	Perrigo Company of Tennessee	515 Eastern Avenue	Allegan	МІ	49010	United States
L. Perrigo Company	Perrigo Corporation Designated Activity Company	Treasury Building	Lower Grand Canal St.	Dublin	2	Ireland
L. Perrigo Company	Perrigo Florida, Inc.	515 Eastern Avenue	Allegan	МІ	49010	United States
L. Perrigo Company	Perrigo LLC	515 Eastern Avenue	Allegan	МІ	49010	United States
L. Perrigo Company	Perrigo New York, Inc.	1625 Bathgate Avenue	Bronx	NY	10457	United States
L. Perrigo Company	Perrigo Pharma International Designated Activity Company	Treasury Building, Lower Grand Canal St.	Dublin		2	Ireland
L. Perrigo Company	Perrigo Pharmaceuticals Company	515 Eastern Avenue	Allegan	МІ	49010	United States
Lannett Company, Inc.	Lannett Company, Inc.	13200 Townsend Rd	Philadelphia	PA	19154	United States
Lannett Company, Inc.	Cody Laboratories	601 Yellowstone Avenue	Cody	WY	82414	United States
Lannett Company, Inc.	Kremers Urban Pharmaceuticals Inc.	1101 C Avenue West	Seymour	IN	47274	United States
Lannett Company, Inc.	Silarx Pharmaceuticals	1033 Stoneleigh Avenue	Carmel	NY	10512	United States
Leadiant Biosciences, Inc.	Leadiant Biosciences, Inc.	9841 Washingtonian Blvd., Suite 500	Gaithersburg	MD	20878	United States
LEO Pharma A/S	LEO Pharma A/S	7 Giralda Farms 2nd Floor	Madison	NJ	07940	United States
LEO Pharma A/S	LEO Pharma Inc.	7 Giralda Farms, 2nd Floor	Madison	NJ	07940	United States

Parent Company	Company Name	Address	City	State	Zip	Country
LF Beauty/ Lornamead	LF Beauty/ Lornamead	1359 Broadway, 17th Floor	New York	NY	10018	United States
LF Beauty/ Lornamead	Lornamead Inc.	175 Cooper Avenue	Tonawanda	NY	14150	United States
Lundbeck LLC	Lundbeck LLC	Six Parkway N Ste 400	Deerfield	IL	60015	United States
Lupin Pharmaceuticals. Inc	Lupin Pharmaceuticals. Inc	111 S. Calvert St.	Baltimore	MD	21202	United States
Lupin Pharmaceuticals. Inc	GAVIS Pharma LLC	400 Campus Drive	Somerset	NJ	08873	United States
Lupin Pharmaceuticals. Inc	GAVIS Pharmaceuticals LLC	400 Campus Drive	Somerset	NJ	08873	United States
Lupin Pharmaceuticals. Inc	Lupin Ltd.					
Lupin Pharmaceuticals. Inc	Lupin Pharmaceuticals, Inc.	111 S. Calvert St.	Baltimore	MD	21202	United States
Lupin Pharmaceuticals. Inc	Novel Laboratories Inc.	400 Campus Drive	Somerset	NJ	08873	United States
Mallinckrodt Pharmaceuticals	Mallinckrodt Pharmaceuticals	675 McDonnell Blvd.	Hazelwood	МО	63042	United States
Matrixx Initiatives, Inc.	Matrixx Initiatives, Inc.	440 Rt. 22 E, Suite 130	Bridgewater	NJ	08807	United States
Mayne Pharma Inc.	Mayne Pharma Inc.	1240 Sugg Parkway	Greenville	NC	27834	United States
Mayne Pharma Inc.	Libertas Pharma Inc	1240 Sugg Parkway	Greenville	NC	27834	United States
Mayne Pharma Inc.	Metrics Inc DBA Mayne Pharma	1240 Sugg Parkway	Greenville	NC	27834	United States
Merck & Co., Inc.	Merck & Co., Inc.	351 N. Sumneytown Pike, P.O. Box 1000, UG3A-90	North Wales	РА	19454	United States
Merck & Co., Inc.	Cherokee Pharmaceutical LLC	100 Avenue C	Riverside	РА	17868	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Merck & Co., Inc.	Cubist Pharmaceuticals	55 Hayden Avenue	Lexington	МА	02421	United States
Merck & Co., Inc.	Intervet, Inc., doing business as Merck Animal Health	2 Giralda Farms	Madison	NJ	07940	United States
Merck & Co., Inc.	Merck Sharp & Dohme Corp.	2000 Galloping Hill Rd	Kenilworth	NJ	07033- 1328	United States
Merck & Co., Inc.	Organon Teknika Corporation, LLC	100 Rudolphe St, Building 1300	Durham	NC	37172	United States
Merck & Co., Inc.	Organon Teknika LLC	100 Rodolphe Street, Building 1300	Durham	NC	37172	United States
Merz North America, Inc.	Merz North America, Inc.	6501 Six Forks Road	Raleigh	NC	27615	United States
Merz North America, Inc.	Merz N.A. f/k/a Merz Aesthetics, Inc	6501 Six Forks Road	Raleigh	NC	27615	United States
Merz North America, Inc.	Merz North America, Inc.	13900 Grandview Parkway	Sturtevant	WI	53177	United States
Merz North America, Inc.	Merz Pharmaceuticals, LLC	6501 Six Forks Road	Raleigh	NC	27615	United States
Micro Labs USA Inc	Micro Labs USA Inc	106 Allen Rd, Ste 102	Basking Ridge	NJ	07920- 3851	United States
Midatech Pharma US Inc.	Midatech Pharma US Inc.	Forum I, 8601 Six Forks Rd Ste 400	Raleigh	NC	27615- 2965	United States
Mikart, LLC	Mikart, LLC	1750 Chatahoochee Ave NW	Atlanta	GA	30318	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Mission Pharmacal Company	Mission Pharmacal Company	P.O. Box 786099	San Antonio	TX	78278- 6099	United States
Mission Pharmacal Company	Prosolus, Inc.	6701 NW 7th St Ste 165	Miami	FL	33126- 6032	United States
Mist Pharmaceuticals, LLC		11 Commerce Drive, Suite 100	Cranford	NJ	07016	United States
Moberg Pharma North America LLC	Moberg Pharma North America LLC	7 E Frederick Place, Suite 100	Cedar Knolls	NJ	07927	United States
Mylan Inc.	Alphapharm Pty Ltd	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	DPT Laboratories LTD (DD)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	DPT Laboratories LTD (JS)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Consumer Healthcare, Inc. (fka Meda Consumer Healthcare Inc.)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Galway	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Inc. (IL)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Inc. (TX)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Mylan Inc.	Mylan Institutional LLC	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (1606-1609JP)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (20/21JP)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (BL)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (F4/F12OSD)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (H12/H13OSD)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (OTL)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SF)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SFF)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SPD)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan LLC	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Mylan Inc.	Mylan Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Specialty L.P.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Technologies, Inc.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan.D.T., Inc. (fka Renaissance Pharma, Inc.)	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Prestium Pharma, Inc.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Somerset Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Wallace Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs, 781 Chestnut Ridge Rd	Morgantown	WV	26505- 2772	United States
Neos Therapeutics, Inc.	Neos Therapeutics, Inc.	2940 N State Highway 360 Ste 400	Grand Prairie	TX	75050- 6424	United States
Neos Therapeutics, Inc.	Neos Therapeutics Brand LLC	2940 N. State Highway 360, Suite 400	Grand Prairie	TX	75050	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation	4500 12th Street Ext	West Columbia	SC	29172- 3025	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 1	840 S. 67th Avenue	Phoenix	AZ	85043	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 2	78 Spruce Street	Murray	KY	42071	United States
Neurocrine Biosciences, Inc.	Neurocrine Biosciences, Inc.	12780 El Camino Real	San Diego	CA	92130	United States
Nexgen Pharma, Inc.	Nexgen Pharma, Inc.	46 Corporate Park, Suite 100	Irvine	СА	92606	United States
NEXTSOURCE BIOTECHNOLOGY LLC	NEXTSOURCE BIOTECHNOLOGY LLC	80 SW 8th St Ste 2660	Miami	FL	33130	United States
Novartis Group Companies	Novartis Group Companies	59 Route 10	East Hanover	NJ	07936	United States
Novartis Group Companies	Alcon Laboratories, Inc.	6740 Business Parkway	Elkridge	MD	21075	United States
Novartis Group Companies	Eon Labs, Inc.	4700 Sandoz Drive	Wilson	NC	27893	United States
Novartis Group Companies	Fougera Pharmaceuticals Inc.	60 Baylis Road	Melville	NY	11747	United States
Novartis Group Companies	Novartis Pharmaceuticals Corporation	1 Health Plaza	East Hanover	NJ	07936-1016	United States
Novartis Group Companies	Sandoz Inc.	100 College Road West	Princeton	NJ	08540	United States
Noven Pharmaceuticals, Inc.	Noven Pharmaceuticals, Inc.	11960 SW 144th St	Miami	FL	33186	United States
Noven Pharmaceuticals, Inc.	Hisamitsu America, Inc.	100 Campus Drive, Suite 117	Florham Park	NJ	07932	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Noven Pharmaceuticals, Inc.	Noven Therapeutics, LLC	11960 NW 144th St	Miami	FL	33186	United States
Novo Nordisk Inc.	Novo Nordisk Inc.	800 Scudders Mill Road	Plainsboro	NJ	08536	United States
Optinose US, Inc.	Optinose US, Inc.	1020 Stony Hill Road, Suite 300	Yardley	PA	19067	United States
OrchidPharma, Inc.	OrchidPharma, Inc.	4 Independence Way Ste 125	Princeton	NJ	08540	United States
OrchidPharma, Inc.	Orchid Pharma Ltd.	313 Valluvar Kottam High Rd	Nungambakkam	Chennai	600 034	India
Orexigen Therapeutics, Inc.	Orexigen Therapeutics, Inc.	3344 N. Torrey Pines Court, Suite 200	La Jolla	CA	92037	United States
Otsuka America Pharmaceutical, Inc.	Otsuka America Pharmaceutical, Inc.	508 Carnegie Center	Princeton	NJ	08540	United States
PARI Respiratory Equipment, Inc.	PARI Respiratory Equipment, Inc.	2412 Pari Way	Midlothian	VA	23112	United States
Pegasus Laboratories, Inc.	Pegasus Laboratories, Inc.	8809 Ely Road	Pensacola	FL	32514	United States
Pfizer Inc.	Pfizer Inc.	235 East 42nd Street, MS 219-5	New York	NY	10017	United States
Pfizer Inc.	Greenstone LLC	100 Route 206 North	Peapack	NJ	07977	United States
Pfizer Inc.	Hospira	275 N. Fields Drive	Lake Forest	IL	60045	United States
Pfizer Inc.	Meridian Medical Technologies, Inc.	8030 Litzinger Road	St. Louis	МО	63144	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Pfizer Inc.	Pfizer Consumer Health	235 East 42nd Street, MS 219-5	New York	NY	10017	United States
Pharmasphere, Inc.	Pharmasphere, Inc.	120 Route 17 North	Paramus	NJ	07652	United States
Pharmasphere, Inc.	Pharma-C, LLC	120 Route 17 North	Paramus	NJ	07652	United States
Pharmasphere, Inc.	WG Critical Care, LLC	120 Route 17 North	Paramus	NJ	07652	United States
Pharming Healthcare Inc.	Pharming Healthcare Inc.	685 Route 202/206, Suite 202	Bridgewater	NJ	08807	United States
Prestige Consumer Healthcare, Inc.	Prestige Consumer Healthcare, Inc.	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Consumer Healthcare, Inc.	C.B. Fleet Company, Inc.	4615 Murray Place	Lynchburg	VA	24502	United States
Prestige Consumer Healthcare, Inc.	C.B. Fleet Company, Incorporated	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Consumer Healthcare, Inc.	DenTek Oral Care, Inc.	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Consumer Healthcare, Inc.	Insight Pharmaceuticals Corporation	660 White Plains Rd Ste 250	Tarrytown	NY	10591-5171	United States
Prestige Consumer Healthcare, Inc.	Insight Pharmaceuticals LLC	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Consumer Healthcare, Inc.	Medtech Products Inc.	660 White Plains Road, 2nd Floor	Tarrytown	NY	10591	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Prestige Consumer Healthcare, Inc.	Prestige Brands, Inc.	660 White Plains Road, Suite 205	Tarrytown	NY	10591	United States
Primus Pharmaceuticals, Inc.	Primus Pharmaceuticals, Inc.	7373 N Scottsdale Rd. B-200	Scottsdale	AZ	85253	United States
Product Quest Mfg.	Product Quest Mfg.	330 Carswell Avenue	Daytona Beach	FL	32117	United States
PuraCap International, LLC	Epic Pharma, LLC	227-15N, Conduit Ave.	Laurelton	NY	11413	United States
PuraCap International, LLC	PuraCap Caribe	Carr 698 km 0.8	Bo Mameyal Dorado	Puerto Rico	00646	United States
PuraCap International, LLC	PuraCap Laboratories LLC dba Blu Pharmaceuticals	301 Robey St.	Franklin	KY	42134	United States
PuraCap International, LLC	PuraCap Pharmaceuticals, LLC	20 Kingsbridge Rd	Piscataway	NJ	08854	United States
Purdue Pharma L.P.	Purdue Pharma L.P.	One Stamford Forum	Stamford	СТ	06901	United States
Purdue Pharma L.P.	Purdue Pharmaceuticals L.P.	4701 Purdue Drive	Wilson	NC	27893	United States
Purdue Pharma L.P.	Purdue Products L.P.	One Stamford Forum	Stamford	СТ	06901	United States
Purdue Pharma L.P.	Rhodes Pharmaceuticals L.P.	498 Washington Street	Coventry	RI	02816	United States
RB Health (US) LLC	RB Health (US) LLC	399 Interpace Parkway	Parsippany	NJ	07054	United States
Regeneron Pharmaceuticals, Inc	Regeneron Pharmaceuticals, Inc	777 Old Saw Mill River Rd	Tarrytown	NY	10591	United States
Regeneron Pharmaceuticals, Inc	Regeneron Healthcare Solutions, Inc	745 Old Saw Mill River Rd	Tarrytown	NY	10591	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Regeneron Pharmaceuticals, Inc	Regeneron Ireland Unlimited Company	Raheen Business Park	Limerick			United States
Relypsa, Inc.	Relypsa, Inc.	100 Cardinal Way	Redwood City	СА	94063	United States
Roche Holdings	Roche Holdings	1 Dna Way	South San Francisco	CA	94080- 4918	United States
Roche Holdings	Genentech USA, Inc.	Genetech, Inc., 1 DNA Way	South San Francisco	CA	94080- 4990	United States
Roche Holdings	Genentech, Inc.	Hoffman-La Roche Inc., 1 DNA Way	South San Francisco	CA	94080- 4990	United States
Sanofi-Aventis US LLC.	Sanofi-Aventis US LLC.	55 Corporate Drive	Bridgewater	NJ	08807	United States
Sanofi-Aventis US LLC.	Chattem, Inc.	1715 West 38th St.	Chattanooga	TN	37409	United States
Sebela Pharmaceuticals Inc.	Sebela Pharmaceuticals Inc.	645 Hembree Pkwy, Suite I	Roswell	GA	30076	United States
Sebela Pharmaceuticals Inc.	Affordable Pharmaceuticals LLC	60 Columbian St. West Suite 200, P.O. Box 850253	Braintree	МА	02185- 0253	United States
Sebela Pharmaceuticals Inc.	Braintree Laboratories Inc.	60 Columbian Street West, P.O. Box 850929	Braintree	МА	02185- 0929	United States
Shionogi Inc.	Shionogi Inc.	300 Campus Dr.	Florham Park	ИЛ	07932	United States
Shire Pharmaceuticals LLC	Shire Pharmaceuticals LLC	300 Shire Way	Lexington	МА	02421	United States
Shire Pharmaceuticals LLC	Baxalta US Inc.	300 Shire Way	Lexington	МА	02421	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Shire Pharmaceuticals LLC	Dyax Corporation	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire Human Genetic Therapies, Inc.	300 Shire Way	Lexington	МА	02421	United States
Shire Pharmaceuticals LLC	Shire LLC	9200 Brookfield Court	Florence	KY	41042	United States
Shire Pharmaceuticals LLC	Shire NPS Pharmaceuticals (f/k/a NPS Pharmaceuticals, Inc.)	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire Orphan Therapies Inc.	300 Shire Way	Lexington	МА	02421	United States
Shire Pharmaceuticals LLC	Shire US Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire US Manufacturing Inc.	1200 Morris Drive	Wayne	PA	19087	United States
Shire Pharmaceuticals LLC	Shire ViroPharma, Inc.	300 Shire Way	Lexington	МА	02421	United States
Shire Pharmaceuticals LLC	ViroPharma Biologics Inc.	300 Shire Way	Lexington	МА	02421	United States
SigmaPharm Laboratories LLC	SigmaPharm Laboratories LLC	3375 Progress Drive	Bensalem	PA	19020	United States
Silvergate Pharmaceuticals, Inc.	Silvergate Pharmaceuticals, Inc.	7300 W 110th St Ste 950	Overland Park	KS	66210- 2394	United States
Smith & Nephew, Inc. (Smith & Nephew Biotherapeutics)	Smith & Nephew, Inc. (Smith & Nephew Biotherapeutics)	Attn: David Mize, VP Dist, Finance, 5600 Clearfork Main St., Suite 600	Ft. Worth	TX	76107	United States
Stallergenes Greer	Stallergenes Greer	179 Lincoln St Ste 303	Boston	МА	02111	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Stallergenes Greer	Stallergenes Greer	639 Nuway Circle NE	Lenoir	NC	28645	United States
Sun Pharmaceutical Industries, Inc.	Sun Pharmaceutical Industries, Inc.	270 Prospect Plains Road	Cranbury	NJ	08512	United States
Sun Pharmaceutical Industries, Inc.	AR Scientific, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	Caraco Pharma, Inc.	270 Prospect Plains Road	Cranbury	NJ	08512	United States
Sun Pharmaceutical Industries, Inc.	Chattem Chemicals, Inc.	3708 St. Elmo Avenue	Chattanooga	TN	37409	United States
Sun Pharmaceutical Industries, Inc.	Dungan Mutual Associates, LLC	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	DUSA Pharmaceuticals New York, Inc.	25 Upton Drive	Wilmington	МА	01887	United States
Sun Pharmaceutical Industries, Inc.	DUSA Pharmaceuticals, Inc.	25 Upton Drive	Wilmington	МА	01887	United States
Sun Pharmaceutical Industries, Inc.	Mutual Pharmaceutical Company, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	Ohm Laboratories Inc.	14 Terminal Road	New Brunswick	NJ	08901	United States
Sun Pharmaceutical Industries, Inc.	Pharmalucence, Inc.	29 Dunham Road	Billerica	МА	01821	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Sun Pharmaceutical Industries, Inc.	Ranbaxy Laboratories Limited	600 College Road East, Suite 2100	Princeton	NJ	08540	United States
Sun Pharmaceutical Industries, Inc.	Sirius Laboratories, Inc.	25 Upton Drive	Wilmington	МА	01887	United States
Sun Pharmaceutical Industries, Inc.	Taro Pharmaceuticals U.S.A., Inc.	3 Skyline Drive	Hawthorne	NY	10532	United States
Sun Pharmaceutical Industries, Inc.	United Research Laboratories, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	URL Pharma, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	URL PharmPro, LLC	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sunovion Pharmaceuticals Inc.	Sunovion Pharmaceuticals Inc.	84 Waterford Dr	Marlborough	МА	01752-7010	United States
Sunstar Americas, Inc.	Sunstar Americas, Inc.	301 East Central Road	Schaumburg	IL	60195	United States
Supernus Pharmaceuticals, Inc.	Supernus Pharmaceuticals, Inc.	1550 E. Gude Drive	Rockville	MD	20850	United States
Takeda Pharmaceuticals U.S.A., Inc.	Takeda Pharmaceuticals America, Inc.	One Takeda Parkway	Deerfield	IL	60015	United States
Takeda Pharmaceuticals U.S.A., Inc.	Millennium Pharmaceuticals, Inc. (d/b/a Takeda Oncology)	40 Lansdowne Street	Cambridge	МА	02139	United States
Takeda Pharmaceuticals U.S.A., Inc.	Takeda Pharmaceuticals America, Inc.	One Takeda Parkway	Deerfield	IL	60015	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Tec Laboratories, Inc.	Tec Laboratories, Inc.	7100 Tec Labs Way SW	Albany	Oregon	97321	United States
TerSera Therapeutics LLC	TerSera Therapeutics LLC	Two Conway Park, 150 N. Field Drive, Suite 195	Lake Forest	IL	60045	United States
TESARO, Inc.	TESARO, Inc.	1000 Winter Street North, Suite 3300	Waltham	МА	02451	United States
Teva Pharmaceuticals USA, Inc.	Teva Pharmaceuticals USA, Inc.	1090 Horsham Rd	North Wales	PA	19454-1505	United States
Teva Pharmaceuticals USA, Inc.	Actavis Generics	400 Interpace Pkwy	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Barr Pharmaceuticals, Inc.	Morris Corporate Center III, 400 Interpace Pkwy	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Cephalon, Inc.	Morris Corporate Center III, 400 Interpace Pkwy	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Teva Neuroscience Inc.	11100 Nail Ave	Overland Park	KS	66221	United States
The Mentholatum Company	The Mentholatum Company	707 Sterling Drive	Orchard Park	NY	14127	United States
The Mentholatum Company	Mentholatum (China) Pharmaceuticals Co., Ltd.	The Second Industrial Estates	Sanxiang, Zhongshan	Guangd ong	528463	China
The Mentholatum Company	Rohto Pharmaceutical Co. Ltd.	7-3 Yumegaoka, Ige	Mie		518-0131	Japan
The Procter & Gamble Company	The Procter & Gamble Company	1 Procter & Gamble Plaza	Cincinnati	ОН	45202	United States
The Ritedose Corporation (TRC)	The Ritedose Corporation (TRC)	1 Technology Circle	Columbia	SC	29203	United States

Parent Company	Company Name	Address	City	State	Zip	Country
TherapeuticsMD, Inc.	TherapeuticsMD, Inc.	6800 Broken Sound Parkway NW, 3rd Fl	Boca Raton	FL	33487	United States
Theratechnologies Inc.	Theratechnologies Inc.	2015 Peel Street, 5th Floor	Montreal	Quebec	H3A1T8	Canada
TOLMAR, Inc.	TOLMAR, Inc.	701 Centre Avenue	Fort Collins	СО	80526	United States
Trigen Laboratories, LLC	Trigen Laboratories, LLC	400 Crossing Blvd	Bridgewater	NJ	08807	United States
Trigen Laboratories, LLC	Vertical Pharmaceuticals, LLC	400 Crossing Blvd	Bridgewater	NJ	08807	United States
Tris Pharma, Inc.	Tris Pharma, Inc.	2033 Route 130	Monmouth Junction	NJ	08852	United States
UCB Inc.	UCB Inc.	1950 Lake Park Drive	Smyrna	GA	30080	United States
UCB Inc.	Upstate Pharma LLC	1950 Lake Park Drive	Smyrna	GA	30080	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Pharmaceuticals (USA), Inc.	777 Terrace Avenue, Ste. 102	Hasbrouck Heights	NJ	07664	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Laboratories Limited	777 Terrace Avenue	Hasbrouk Heights	NJ	07604	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Laboratories Limited	777 Terrace Avenue, Ste 102	Hasbrouck Heights	NJ	07604	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Pharmaceuticals (USA), Inc.	777 Terrace Avenue, Ste. 102	Hasbrouck Heights	NJ	07664	United States
Upsher-Smith Laboratories, LLC	Upsher-Smith Laboratories, LLC	6701 Evenstad Dr.	Maple Grove	MN	55369	United States

Parent Company	Company Name	Address	City	State	Zip	Country
Validus Pharmaceuticals LLC	Validus Pharmaceuticals LLC	119 Cherry Hill Road, Ste 310	Parsippany	NJ	07054	United States
Vertex Pharmaceuticals Incorporated	Vertex Pharmaceuticals Incorporated	50 Northern Avenue	Boston	МА	02210	United States
Vi-Jon, Inc.	Vi-Jon, Inc.	8515 Page Ave	St. Louis	МО	63114	United States
VIVUS, Inc.	VIVUS, Inc.	900 E Hamilton Ave Ste 550	Campbell	CA	95008- 0643	United States
WellSpring Pharmaceutical Corporation	WellSpring Pharmaceutical Corporation	5911 N. Honore Avenue, Suite 211	Sarasota	FL	34243	United States
Welmedix Consumer Healthcare	Welmedix Consumer Healthcare	103 Carnegie Center, Suite 200	Princeton	NJ	08540	United States
Wisconsin Pharmacal Company, LLC	Wisconsin Pharmacal Company, LLC	1 Pharmacal Way	Jackson	WI	53037	United States
Wisconsin Pharmacal Company, LLC	Lake Consumer Products, Inc. (subsidiary of Wisconsin Pharmacal)	1 Pharmacal Way	Jackson	WI	53037	United States
Wockhardt USA LLC	Wockhardt USA LLC	20 Waterview Blvd, 3rd Floor	Parsippany	NJ	07054	United States
Wockhardt USA LLC	Morton Grove Pharmaceuticals, Inc.	6451 Main Street	Morton Grove	IL	60053	United States
Wockhardt USA LLC	Wockhardt Limited	Wockhardt Towers, Bandra Kurla Complex	Bandra (E)	Mumbai	400051	India
Wockhardt USA LLC	Wockhardt USA LLC	20 Waterview Blvd., 3rd Floor	Parsippany	NJ	07054	United States

Parent Company	Company Name	Address	City	State	Zip	Country
X-GEN Pharmaceuticals, Inc.	X-GEN Pharmaceuticals, Inc.	300 Daniel Zenker Drive	Horseheads	NY	14845	United States
Xttrium Laboratories, Inc.	Xttrium Laboratories, Inc.	1200 E. Business Center Dr	Mount Prospect	IL	60056	United States
Zoetis	Zoetis	One Pfizer Way	Lee's Summit	МО	64081	United States
Zydus Pharmaceuticals USA Inc	Zydus Pharmaceuticals USA Inc	73 Route 31 North	Pennington	NJ	08534	United States
Zydus Pharmaceuticals USA Inc	Sentynl Therapeutics, Inc.	420 Stevens Ave, Suite 200	Solana Beach	CA	92075	United States

Appendix B

Sample Contact List for Outreach and Education to the Community

The following are Associations, Agencies, and Organizations that will be contacted for assistance with outreach and education to the community.

Health Systems:

County of San Mateo Health System
Hospital Consortium of San Mateo
Health Plan of San Mateo
San Mateo Medical Center
Kaiser Permanente Medical Center
Lucile S. Packard Children's Hospital
Mills-Peninsula Health Services
Sequoia Hospital
Seton Medical Center

Stanford Hospitals and Clinics
Stanford Medicine Outpatient Center
Veterans Affairs Palo Alto Health Care System

San Bruno VA Outpatient Clinic

Health Associations and Societies:

California State Board of Pharmacy
California Pharmacists Association
The Medical Board of California
California Nurses Association
National Association of Social Workers California
Chapter
California Board of Registered Nursing
California Board of Vocational Nursing

California Department of Health Care Services California Health and Human Services Agency San Mateo County Pharmacists Association

San Mateo County Medical Association

Organizations, Districts, and Agencies:

San Mateo Department of Public Health San Mateo Public Works Human Services Agency of San Mateo University Systems and Campuses San Mateo Fire Department

American Medical Response San Mateo

CalRecycle Recology

RecycleWhere.org

Veterinary Facilities and Hospitals:

VCA San Mateo Animal Hospital
North Peninsula Veterinary Emergency Clinic
South Hillsdale Animal Hospital
VCA Bayshore Animal Hospital
SAGE Centers for Veterinary Specialty &
Emergency Care
Banfield Pet Hospital
Aragon Veterinary Clinic Inc.
Peninsula Avenue Veterinary Clinic

Crystal Springs Pet Hospital
Laurelwood Veterinary Clinic
Animal Cove Pet Hospital
VCA San Carlos Animal Hospital
Spruce Avenue Pet Hospital

Appendix C

Participating and Interested Kiosk Drop-Off Sites

MED-Project maintains regular contact with Kiosk Drop-Off Site Hosts actively participating in the Program. MED-Project will provide Kiosk Drop-Off Site Hosts with the materials described in Section XI.D.3 and with instructional materials about servicing kiosks or requesting kiosk maintenance no less than semi-annually.

Site Name	Address	City	District	Status
BURLINGAME POLICE DEPT	1111 TROUSDALE DR	BURLINGAME	1	PARTICIPATING
CVS/PHARMACY #09807	10 BAYHILL SHOPPING CTR	SAN BRUNO	1	PARTICIPATING
CVS/PHARMACY #09811	1871 EL CAMINO REAL	BURLINGAME	1	PARTICIPATING
CVS/PHARMACY #09940	872 N DELAWARE ST	SAN MATEO	1	PARTICIPATING
HILLSBOROUGH POLICE DEPT	1600 FLORIBUNDA AVE	HILLSBOROUGH	1	PARTICIPATING
KAISER HEALTH PLAN #353	801 TRAEGER AVE	SAN BRUNO	1	PARTICIPATING
KAISER PERMANENTE #357	901 EL CAMINO REAL	SAN BRUNO	1	PARTICIPATING
KAISER PERMANENTE SOUTH SAN FRANCISCO MEDICAL CENTER #351	1200 EL CAMINO REAL	SOUTH SAN FRANCISCO	1	PARTICIPATING
SAN BRUNO POLICE DEPT	1177 HUNTINGTON AVE	SAN BRUNO	1	PARTICIPATING
SAN MATEO COUNTY PROBATION DEPT	1024 MISSION RD	SOUTH SAN FRANCISCO	1	PARTICIPATING
SAN MATEO COUNTY YOUTH PROBATION SERVICES	222 PAUL SCANNELL DR	SAN MATEO	1	PARTICIPATING

Site Name	Address	City	District	Status
SOUTH SAN FRANCISCO POLICE DEPT	33 ARROYO DR	SOUTH SAN FRANCISCO	1	PARTICIPATING
SUNSHINE PHARMACY	1166 MISSION RD	SOUTH SAN FRANCISCO	1	PARTICIPATING
MILBRAE POLICE BUREAU	581 MAGNOLIA AVE	MILLBRAE	1	PARTICIPATING
CVS/PHARMACY #09554	77 BOVET RD	SAN MATEO	2	PARTICIPATING
CVS/PHARMACY #09833	4242 S EL CAMINO REAL	SAN MATEO	2	PARTICIPATING
CVS/PHARMACY #09879	987 E HILLSDALE BLVD	FOSTER CITY	2	PARTICIPATING
CVS/PHARMACY #09977	124 DE ANZA BLVD	SAN MATEO	2	PARTICIPATING
KAISER PERMANENTE PHARMACY #339	1000 FRANKLIN PKWY W	SAN MATEO	2	PARTICIPATING
SAN CARLOS POLICE BUREAU	200 FRANKLIN PKWY	SAN MATEO	2	PARTICIPATING
SAN MATEO MEDICAL CENTER	222 W 39TH	SAN MATEO	2	PARTICIPATING
SAN MATEO NEIGHBORHOOD PHARMACY	9 37TH AVE	SAN MATEO	2	PARTICIPATING
BELMONT POLICE DEPT	ONE TWIN PINES LN	BELMONT	3	PARTICIPATING
CVS/PHARMACY #0550	1324 SAN CARLOS AVE	SAN CARLOS	3	PARTICIPATING
CVS/PHARMACY #9172	11 EL CAMINO REAL	SAN CARLOS	3	PARTICIPATING
CVS/PHARMACY #9216	60 CABRILLO HWY N	HALF MOON BAY	3	PARTICIPATING

Site Name	Address	City	District	Status
HALF MOON BAY RX	40 STONE PINE RD	HALF MOON BAY	3	PARTICIPATING
PACIFICA POLICE DEPT	2075 COAST HWY	PACIFICA	3	PARTICIPATING
SHERIFF - HALF MOON BAY POLICE DEPT	537 KELLY AVE	HALF MOON BAY	3	PARTICIPATING
SHERIFF - NORTH COAST MOSS BEACH SUB- STATION	500 CALIFORNIA AVE	MOSS BEACH	3	PARTICIPATING
SHERIFF - SAN CARLOS POLICE DEPT	600 ELM ST	SAN CARLOS	3	PARTICIPATING
CVS/PHARMACY #09690	1301 BROADWAY ST	REDWOOD CITY	4	PARTICIPATING
CVS/PHARMACY #10240	700 EL CAMINO REAL	MENLO PARK	4	PARTICIPATING
CVS/PHARMACY #9329	1039 EL CAMINO REAL	REDWOOD CITY	4	PARTICIPATING
DREW PHARMACY	2111B UNIVERSITY AVE	EAST PALO ALTO	4	PARTICIPATING
EAST PALO ALTO POLICE DEPT	141 DEMETER ST	EAST PALO ALTO	4	PARTICIPATING
KAISER HEALTH PLAN #371	1150 VETERANS BLVD	REDWOOD CITY	4	PARTICIPATING
KAISER HEALTH PLAN BIRCH PHARMACY #372	910 MARSHALL ST	REDWOOD CITY	4	PARTICIPATING
MENLO PARK POLICE DEPT	701 LAUREL ST	MENLO PARK	4	PARTICIPATING
PROBATION DEPT - EAST PALO ALTO	2415 UNIVERSITY AVE	EAST PALO ALTO	4	PARTICIPATING
REDWOOD CITY POLICE DEPT	1301 MAPLE ST	REDWOOD CITY	4	PARTICIPATING
SAN MATEO COUNTY SHERIFF'S OFFICE	400 COUNTY CENTER	REDWOOD CITY	4	PARTICIPATING

Site Name	Address	City	District	Status
BRISBANE POLICE DEPT	50 PARK PL	BRISBANE	5	PARTICIPATING
BROADMOOR POLICE DEPT	388 88TH ST	BROADMOOR	5	PARTICIPATING
CHINESE HOSPITAL PHARMACY	386 GELLERT BLVD	DALY CITY	5	PARTICIPATING
CVS/PHARMACY #10165	135 PIERCE ST	DALY CITY	5	PARTICIPATING
CVS/PHARMACY #9752	375 GELLERT BLVD	DALY CITY	5	PARTICIPATING
DALY CITY POLICE DEPT	333 90TH ST	DALY CITY	5	PARTICIPATING
KAISER PERMANENTE PHARMACY #341	395 HICKEY BLVD	SOUTH SAN FRANCISCO	5	PARTICIPATING
NEMS - EASTMOOR	211 EASTMOOR AVE	DALY CITY	5	PARTICIPATING
RITE AID 05885	170 SAN MATEO ROAD	HALF MOON BAY	3	INTERESTED
RITE AID 05890	1400 LINDA MAR BOULEVARD	PACIFICA	3	INTERESTED
RITE AID 05891	200 FAIRMONT SHOPPING CENTER	PACIFICA	3	INTERESTED
RITE AID 05892	340 WOODSIDE PLAZA	REDWOOD CITY	4	INTERESTED
RITE AID 05893	2150 ROOSEVELT AVENUE	REDWOOD CITY	4	INTERESTED
RITE AID 05902	666 CONCAR DRIVE	SAN MATEO	2	INTERESTED
RITE AID 05903	1320 WEST HILLSDALE BLVD.	SAN MATEO	2	INTERESTED

Appendix D

Potential Additional Kiosk Drop-Off Sites

Per Ordinance § 4.116.030(e)(2), MED-Project will notify potential Kiosk Drop-Off Sites on an annual basis to inform them of the opportunity to participate in the Program as a Kiosk Drop-Off Site. All sites listed were last contacted on February 28, 2019.

SITE NAME	ADDRESS	CITY	ZIP
1800 SULLIVAN PHARMACY	1800 SULLIVAN AVE STE 102	DALY CITY	94015
ALPHASCRIPT, INC.	1160 INDUSTRIAL RD #17	SAN CARLOS	94070
ANCHOR DRUGS III	161 S SPRUCE AVE	S SAN FRANCISCO	94080
APOTHECARY PHARMACY INC	1500 SOUTHGATE AVE STE 109	DALY CITY	94015
ATHERTON POLICE DEPARTMENT	83 ASHFIELD ROAD	ATHERTON	94027
BERKSHIRE PHARMACY	11 BERKSHIRE AVE	REDWOOD CITY	94061
CALIFORNIA HIGHWAY PATROL	355 CONVENTION WAY	REDWOOD CITY	94063
CARE4U PHARMACY	474 SAN MATEO AVENUE	SAN BRUNO	94066
CHOICECARE PHARMACY INC	90 S SPRUCE STE W	S SAN FRANCISCO	94080
COLMA POLICE DEPARTMENT	1199 EL CAMINO REAL	COLMA	94014
COSTCO PHARMACY #1042	2300 MIDDLEFIELD RD	REDWOOD CITY	94063
COSTCO PHARMACY #147	1001 METRO CENTER BLVD.	FOSTER CITY	94404
COSTCO PHARMACY #422	451 SOUTH AIRPORT BLVD.	SOUTH SAN FRANCISCO	94080
COSTCO WHOLESALE NO 475	1600 EL CAMINO REAL BLVD	SOUTH SAN FRANCISCO	94080
DAVITA RX LLC	1178 CHERRY AVE	SAN BRUNO	94066
FEEL GOOD COMPOUNDERS	411 DONDEE WAY, UNIT C	PACIFICA	94044

SITE NAME	ADDRESS	CITY	ZIP
FOSTER CITY POLICE DEPARTMENT	610 FOSTER CITY BLVD.	FOSTER CITY	94404
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16111	5001 JUNIPERO SERRA BLVD	COLMA	94014
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16112	2485 EL CAMINO REAL	REDWOOD CITY	94063
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16439	1150 EL CAMINO REAL	SAN BRUNO	94066
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16490	2220 BRIDGEPOINTE PKWY	SAN MATEO	94404
GARFIELD BEACH CVS LLC D/B/A TARGET PHARMACY # 16746	133 SERRAMONTE CTR	DALY CITY	94015
HALF MOON BAY POLICE DEPARTMENT	537 KELLY AVE	HALF MOON BAY	94019
JEFFERSON PLAZA PHARMACY	3137 JEFFERSON AVE	REDWOOD CITY	94061
LPCH CHILDREN'S HOME PHARMACY	4600 BOHANNON DR STE 105	MENLO PARK	94025
LUCKY CALIFORNIA PHARMACY # 707	6843 MISSION BLVD	DALY CITY	94014
LUCKY PHARMACY #710	919 EDGEWATER DR	FOSTER CITY	94404
LUCKY PHARMACY #748	1322 EL CAMINO REAL	SAN BRUNO	94066
LUCKY PHARMACY #749	1133 OLD COUNTRY RD	SAN CARLOS	94070
MARINER ADVANCED PHARMACY CORP	43 E 3RD AVE	SAN MATEO	94401
MILLS PENINSULA HEALTH CENTER PHARMACY	100 S. SAN MATEO DRIVE ROOM 110	SAN MATEO	94401
MILLS PENINSULA MEDICAL CENTER PHARMACY	1501 TROUSDALE DR	BURLINGAME	94010
MOBIMEDS	133 ARCH STREET SUITE 7	REDWOOD CITY	94602
NIMBLE PHARMACY	900 WILLOW ROAD	MENLO PARK	94025

SITE NAME	ADDRESS	CITY	ZIP
NOB HILL PHARMACY #628	270 REDWOOD SHORES PARKWAY	REDWOOD CITY	94065
PHARMACA INTEGRATIVE PHARMACY	871 SANTA CRUZ AVE	MENLO PARK	94025
PORTOLA VALLEY POLICE DEPARTMENT	400 COUNTRY CENTER	REDWOOD CITY	94063
SAFEWAY PHARMACY #0305	1071 EL CAMINO REAL	REDWOOD CITY	94063
SAFEWAY PHARMACY #0668	2100 RALSTON AVE	BELMONT	94002
SAFEWAY PHARMACY #0747	850 WOODSIDE RD	REDWOOD CITY	94061
SAFEWAY PHARMACY #0970	1655 EL CAMINO REAL	SAN MATEO	94402
SAFEWAY PHARMACY #1138	1100 EL CAMINO REAL	BELMONT	94002
SAFEWAY PHARMACY #1547	1450 HOWARD AVENUE	BURLINGAME	94010
SAFEWAY PHARMACY #2719	525 EL CAMINO REAL	MENLO PARK	94025
SAFEWAY PHARMACY #2878	525 EL CAMINO REAL	MILLBRAE	94030
SAFEWAY PHARMACY #4903	2710 MIDDLEFIELD ROAD	REDWOOD CITY	94063
SEQUOIA HOSPITAL	170 ALAMEDA DE LAS PULGAS	REDWOOD CITY	94062
SETON MEDICAL CENTER	1900 SULLIVAN AVE	DALY CITY	94015
SETON MEDICAL CENTER - COASTSIDE	600 MARINE BLVD	MOSS BEACH	94038
SEVENTEEN FIFTY MEDICAL CENTER PHARMACY	1750 EL CAMINO REAL	BURLINGAME	94010
SOUTH COUNTY COMMUNITY HEALTH CENTER INC DBA RAVENSWOOD FAMILY HE	1885 BAY ROAD	EAST PALO ALTO	94303
STANFORD HEALTH CARE	450 BROADWAY ST	REDWOOD CITY	94063

SITE NAME	ADDRESS	CITY	ZIP
STANFORD HEALTH CARE	450 BROADWAY ST PAVILION A 3RD FL	REDWOOD CITY	94063
TED'S VILLAGE PHARMACY INC	29 WEST 25TH AVE	SAN MATEO	94403
TRIAD ISOTOPES, INC.	806 DUBUQUE AVE	S SAN FRANCISCO	94080
WALGREENS #00063	900 RALSTON AVE	BELMONT	94002
WALGREENS #00324	216 WESTLAKE CENTER	DALY CITY	94015
WALGREENS #00625	615 BROADWAY	MILLBRAE	94030
WALGREENS #01807	22 SAN PEDRO RD	DALY CITY	94014
WALGREENS #02126	1414 EL CAMINO REAL	SAN CARLOS	94070
WALGREENS #02939	333 EL CAMINO REAL	SAN BRUNO	94066
WALGREENS #03296	191 EAST 3RD AVE	SAN MATEO	94401
WALGREENS #03346	399 EL CAMINO REAL	SOUTH SAN FRANCISCO	94080
WALGREENS #05006	4070 S EL CAMINO REAL	SAN MATEO	94403
WALGREENS #05365	6100 MISSION STREET	DALY CITY	94014
WALGREENS #06655	1160 BROADWAY	BURLINGAME	94010
WALGREENS #07087	643 SANTA CRUZ AVE	MENLO PARK	94025
WALGREENS #07970	45 SOUTH EL CAMINO REAL	MILLBRAE	94030
WALGREENS #11261	520 PALMETTO AVE	PACIFICA	94044
WALGREENS #12257	260 EL CAMINO REAL	BURLINGAME	94010
WALGREENS #15397	2238 WESTBOROUGH BLVD	SOUTH SAN FRANCISCO	94080
WOODSIDE OFFICE OF THE SHERIFF	400 COUNTY CENTER, 3RD FLOOR	REDWOOD CITY	94063

Appendix E

Sample Kiosk Prototype and Signage



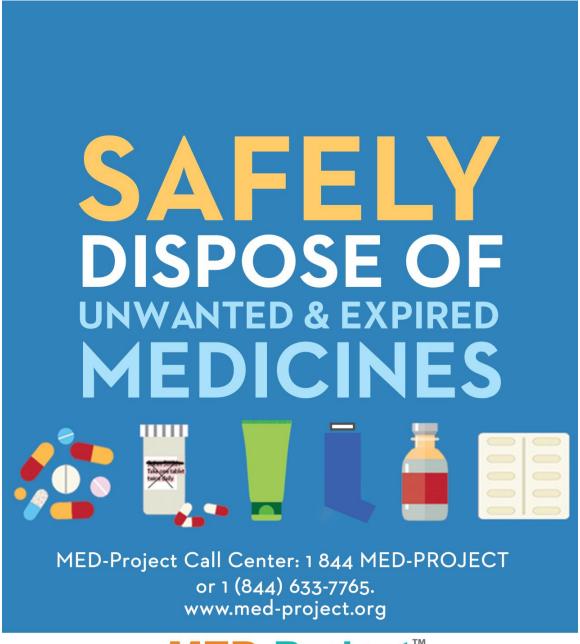


ONLY SCHEDULE II-V CONTROLLED AND NON-CONTROLLED SUBSTANCES THAT ARE LAWFULLY POSSESSED BY THE ULTIMATE USER ARE ACCEPTABLE TO BE PLACED IN THE KIOSK. SCHEDULE I CONTROLLED SUBSTANCES, ILLICIT OR DANGEROUS SUBSTANCES, AND ANY CONTROLLED SUBSTANCES NOT LAWFULLY POSSESSED BY THE ULTIMATE USER MAY NOT BE PLACED IN THE KIOSK.

PROP 65 WARNING: Entering this area, or coming into contact with items or materials in this kiosk, can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

For more information about the MED-Project program, please go to www.med-project.org or call 1-844-MED-PROJECT.





MED-Project[™]
Medication Education & Disposal

Sample Kiosk Signage

Drop-Slot Kiosk Art



Name: 123 Pharmacy

Contact: (555) 555-5555

Sample Mail-Back Services Signage

MED-Project will provide Kiosk Drop-Off Sites with 8.5" x 11" (letter-sized) signage notifying Residents of the opportunity to obtain Injector Mail-Back Packages to dispose of Pre-filled Injector Products that may not be disposed of at Kiosk Drop-Off Sites, in addition to the other signage for Unwanted Medicine.





MAIL-BACK SERVICES ARE AVAILABLE IN YOUR AREA FOR:

HAY SERVICIOS DE DEVOLUCIÓN POR CORREO DISPONIBLES EN SU ZONA PARA:

在您所在地區提供的 寄回服務包括:

AVAILABLE ANG MGA SERBISYO NG MAIL-BACK SA IYONG LUGAR PARA SA:



INJECTORS INYECTORES

注射器 MGA PANG-INIKSYON

Para sa higit pang impormasyon, mangyaring tawagan o bisitahin ang aming website

1-844-MED-PROJECT/www.med-project.org

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.

Appendix F

Request for Approval of Disposal Processes for Unwanted Medicine Collected from Kiosk Drop-Off Sites

MED-PROJECT REQUEST FOR APPROVAL OF DISPOSAL PROCESSES FOR UNWANTED MEDICINE COLLECTED FROM KIOSK DROP-OFF SITES

MED-Project[™]

Medication Education & Disposal

April 15, 2019

MED-PROJECT REQUEST FOR APPROVAL OF DISPOSAL PROCESSES FOR UNWANTED MEDICINE COLLECTED FROM KIOSK DROP-OFF SITES

Pursuant to § 4.116.110(f) of the County of San Mateo Safe Medicine Disposal Ordinance, Ordinance No. 04636, codified at Chapter 4.116 of Title 4 of the San Mateo County Ordinance Code ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Environmental Health Division (the "Director") to use permitted medical waste incinerators and a municipal waste combustor for the disposal of unwanted medicine collected at Kiosk Drop-Off Sites (as defined in the MED-Project Product Stewardship Plan ("Plan") § III) through host-assisted collection. Additionally, MED-Project requests approval from the Director to use a permitted medical waste incinerator for the disposal of unwanted medicine collected at Kiosk Drop-Off Sites through technician-assisted collection. As described below, cost, logistics, and other considerations support approving the disposal of materials collected at Kiosk Drop-Off Sites at permitted medical waste incinerators or a municipal waste combustor, consistent with the intent of Ordinance § 4.116.070(b). Further, exercising discretion to allow for the disposal of materials collected at a permitted medical waste incinerator or municipal waste combustor would achieve the objectives of the Ordinance in accordance with § 4.116.110(f) of the Ordinance.

I. THE PROCESS FOR THE DISPOSAL OF MATERIALS COLLECTED KIOSK DROP-OFF SITES AT THE PROPOSED INCINERATORS

MED-Project is proposing that containers and inner liners for host-assisted Kiosk Drop-Off Sites be provided by Stericycle, Inc. ("Stericycle") and/or Covanta Environmental Solutions, LLC ("Covanta"). MED-Project is proposing that containers and inner liners for technician-assisted Kiosk Drop-Off Sites be provided by Stericycle. All of the containers will be pre-addressed and pre-paid for shipment to a medical waste incinerator or municipal waste combustor. The proposed incinerators will scan the unique identifier on each package to record receipt of the package before incinerating it, and will confirm the materials have been properly incinerated.

A. Stericycle Process

MED-Project is proposing that materials collected at host-assisted collection Kiosk Drop-Off Sites be sent to Stericycle's Indianapolis, Indiana facility (the "Indianapolis Facility")¹ or the Covanta facilities discussed below. From the Indianapolis Facility, the materials will be sent to Stericycle's Warren, Ohio facility (the "Warren Facility")² for destruction via incineration. MED-Project is also proposing that materials collected via technician-assisted collection at Kiosk Drop-Off Sites be sent to the Indianapolis Facility to be forwarded for destruction at the Warren Facility, in addition to hazardous waste incinerators set forth in MED-Project's Plan (Plan § X.D).

The Warren Facility is a permitted hospital, medical, and infectious waste incinerator. The incinerator's primary chamber has a minimum exit gas temperature of 1400 °F, and the incinerator's secondary chamber is operated at over 1,830.5 °F. The Warren Facility also has a Clean Air Act Title V permit, which establishes air emissions limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury, among other chemicals. To control air pollution, the Warren Facility employs a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system, among other controls. The incinerator stack(s) must be designed to minimize the impact of emissions on employees, residents, visitors, and nearby residences.

The County has already approved the use of the Warren Facility for the disposal of Standard Mail-Back Packages. Under this petition, materials collected at Kiosk Drop-Off Sites would be sent to this same medical waste incinerator and subject to the same disposal process.

¹ The Indianapolis Facility's mailing address is 2670 Executive Drive, Suite A, Indianapolis, IN 46241.

² The Warren Facility's mailing address is 1901 Pine Ave SE, Warren, OH 44483.

B. Covanta Process

MED-Project is proposing that materials collected at host-assisted collection Kiosk Drop-Off Sites be sent for incineration at the Curtis Bay Energy, L.P. facility (the "Curtis Bay Facility")³ or the Covanta Lancaster, Inc. facility in Lancaster, Pennsylvania ("Covanta Lancaster"),⁴ in addition to the Warren Facility discussed above.

a. Curtis Bay Facility

The Curtis Bay Facility is a permitted hospital, medical, and infectious waste incinerator. The Curtis Bay Facility operates two incineration units that are permitted to incinerate a maximum of 150 tons of waste per day for the facility. The Curtis Bay Facility operates under a Clean Air Act Title V permit, and is subject to emissions limits for a number of air pollutants in accordance with this permit. To control air pollution, the facility employs a tertiary combustion chamber, a dry injection acid gas scrubber, a powder activated carbon system, and a fabric filter with passive dioxins/furans emissions control.⁵ The facility relies on a continuous opacity monitoring system and a continuous emission monitoring system for monitoring carbon monoxide, oxygen, and hydrogen chloride content levels of the stack exhaust gases.⁶ The Curtis Bay Facility also operates under an Industrial Wastewater Discharge Permit and Solid Waste Permit.

b. Covanta Lancaster

Containers provided by Covanta may be pre-addressed and pre-paid for delivery to the Covanta Manheim, Pennsylvania DEA-registered collector and reverse distributor facility ("Manheim Facility"). From the Manheim Facility, the packages are transported by Doncin Transport, Inc. to Covanta Lancaster for destruction via incineration. *See* Plan § X. Covanta Lancaster will scan the unique identifier on each package to record receipt of the package before incinerating it and will confirm the materials have been properly incinerated.

Covanta Lancaster is a permitted large municipal waste combustor. Covanta Lancaster is an "energy-from-waste" facility that incinerates waste and generates 35.7 megawatts per day from a condensing steam turbine that provides energy to GPU Energy. Covanta Lancaster employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a furnace dry-lime injection system, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. Covanta Lancaster operates under a Title V Clean Air Act permit and a solid waste permit. Covanta Lancaster is a "zero discharge" facility, meaning that the wastewater generated on-site is treated and reused in the waste management process, according to the facility's website. Covanta Lancaster has been designated as a Voluntary Protection Program ("VPP") Star facility by the U.S. Occupational Safety and Health Administration ("OSHA"), recognizing the facility's employer's and employees' exemplary achievement in the prevention and control of occupational safety and health hazards.

³ The Curtis Bay Facility's mailing address is 3200 Hawkins Point Road, Baltimore, MD 21226.

⁴ Covanta Lancaster's mailing address is 1911 River Road, Bainbridge, PA 17502.

⁵ This information is drawn from the Curtis Bay Facility's Title V permit,

http://www.mde.state.md.us/programs/Permits/AirManagementPermits/Test/Curtis%20Bay%20Energy.pdf. 6 Id

⁷ See Covanta, Covanta Lancaster, https://www.covanta.com/Our-Facilities/Covanta-Lancaster.

⁸ See Title V Operating Permit # 36-05013, http://files.dep.state.pa.us/Air/AirQuality/AQPortalFiles/Permits/PermitDocuments/1130890[36-05013]_Issued_v1.pdf.

⁹ See Solid Waste Permit # 400592 PaDEP, https://www.ahs.dep.pa.gov/eFACTSWeb/searchResults_singleFacility.aspx?FacilityID=255039.

II. STANDARDS FOR THE DIRECTOR TO APPROVE THE USE OF THE PROPOSED INCINERATORS FOR THE DISPOSAL OF MATERIALS COLLECTED AT KIOSK DROPOFF SITES

Under Ordinance § 4.116.070(b), the Director may grant approval for a producer or group of producers to dispose of some or all of the collected covered drugs—including those collected at Kiosk Drop-Off Sites—at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

Additionally, in approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance under § 4.116.110(f) in order to achieve the objectives of the Ordinance, which include protecting the environment and public health.

III. DISPOSAL OF MATERIALS COLLECTED AT KIOSK DROP-OFF SITES AT THE PROPOSED INCINERATORS IS SUPPORTED BY COST, LOGISTICS, AND OTHER CONSIDERATIONS.

MED-Project requests approval to use the Warren Facility, Curtis Bay Facility, and Covanta Lancaster (the "Proposed Facilities") for materials collected at Kiosk Drop-Off Sites based on cost, logistics, and other considerations.

First, the cost to dispose of materials collected at Kiosk Drop-Off Sites at a hazardous waste disposal facility is much greater than the cost to dispose of such materials at the Proposed Facilities. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than other incineration facilities to dispose of the same quantity of waste.

Second, MED-Project's vendors have established logistics networks that rely on medical waste incinerators and a municipal waste combustor in addition to any hazardous waste disposal facilities. The processes discussed above are efficient and simple. Use of these medical waste incinerators and a municipal waste combustor would allow MED-Project to ensure redundancy of service in case any of the other approved disposal facilities is ever offline. It would also allow MED-Project to maintain flexibility and control costs.

Third, there are no other laws or requirements, outside of the Ordinance, that would require MED-Project to dispose of materials collected at Kiosk Drop-Off Sites at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at permitted medical waste incinerators or a municipal waste combustor like the proposed incinerators. Any unwanted medicines collected at Kiosk Drop-Off Sites under this Plan are not regulated under California's hazardous waste regulations, and therefore are not required to be treated as hazardous waste. In fact, municipal waste combustors and medical waste incinerators are two of the disposal methods the United States Environmental Protection Agency directs law enforcement agencies to use for the destruction of collected pharmaceutical products. *See* United States Environmental Protection Agency, Management of Household Pharmaceuticals Collected by Law Enforcement During Take-Back Events and Programs at 2, 4 (Sept. 11, 2018).

For the above reasons, the use of Covanta Lancaster should be approved under Ordinance § 4.116.070(b), under which the Director can approve disposal at a municipal waste combustor where disposal at a hazardous waste facility is not feasible based on cost, logistics, and other considerations.

For the same reasons, the use of the Warren Facility and Curtis Bay Facility to dispose of materials collected under the Plan would meet the overall intent of San Mateo County in adopting the standard at Ordinance § 4.116.070(b). It would be consistent with the intent of Ordinance § 4.116.070(b) and within the Director's authority under Ordinance § 4.116.110(f) to allow for disposal at medical waste incinerators that are permitted to receive this waste and that would protect the environment and human health (i.e., the Warren Facility and Curtis Bay Facility). Accordingly, MED-Project requests that the Director approve disposal of materials collected at Kiosk Drop-Off Sites at the Proposed Facilities.

IV. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF MATERIALS COLLECTED AT KIOSK DROP-OFF SITES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.110(F) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of the Proposed Facilities for disposal of materials collected at Kiosk Drop-Off Sites under Ordinance § 4.116.110(f) because disposal at these proposed incinerators would protect the environment and human health in furtherance of the objectives of the Ordinance. *See*, *e.g.*, Ordinance § 4.116.070.

Furthermore, as noted above, the Director should also exercise its discretion to approve medical waste incineration at the Warren Facility and Curtis Bay Facility for materials collected at Kiosk Drop-Off Sites based on cost, logistics, and other considerations, consistent with the intent of Ordinance § 4.116.070(b).

A. Medical waste incinerators

Disposal of materials collected at Kiosk Drop-Off Sites at the proposed medical waste incinerators (i.e., the Warren Facility and the Curtis Bay Facility) would protect the environment and human health. These medical waste incinerators are subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The proposed incinerators are subject to environmental permits, including Clean Air Act Title V permits for air emissions and state solid waste management permits. In addition, they have extensive air pollution controls in place. Additionally, facilities that handle medical waste, like the proposed medical waste incinerators, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

As these applicable requirements protect the environment and human health, the Director should exercise its discretion under Ordinance § 4.116.110(f) to approve the Warren Facility and the Curtis Bay Facility for the disposal of materials collected at Kiosk Drop-Off Sites. Such approval would also be consistent with the intent of Ordinance § 4.116.070(b) to allow other disposal options should hazardous waste disposal facilities prove not feasible.

B. Municipal waste combustor

Disposal at Covanta Lancaster would protect the environment and human health. Covanta Lancaster has extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. It has also been recognized for its workplace safety achievements, as evidenced by its status as a VPP Star facility.

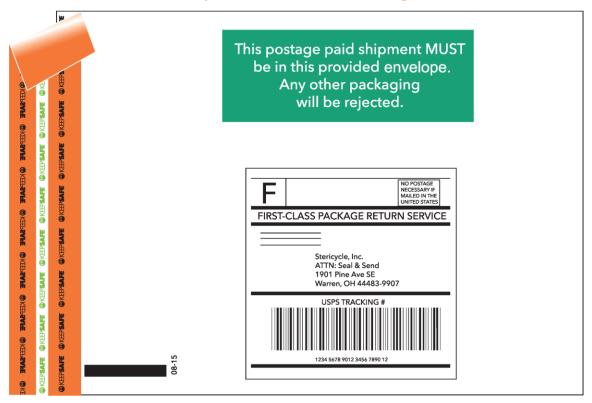
As these applicable requirements and measures protect the environment and human health, the Director should exercise its discretion under Ordinance § 4.116.110(f) to approve Covanta Lancaster as the disposal site for materials from Kiosk Drop-Off Sites.

V. CONCLUSION

The Director should approve the disposal of materials collected at Kiosk Drop-Off Sites via incineration at the Proposed Facilities as proposed by MED-Project pursuant to and consistent with Ordinance §§ 4.116.070(b) and 4.116.110(f).

Appendix G

Sample Standard Mail-Back Package



Description:

Plastic envelope with return label and instructional flyer, and unique identifier enabling tracking at collection and disposal

Package Size:

Outer dimensions: 8.25" x 12"; inner dimensions: 7.375" x 10.375"; 2" flap with tamper-evident hot melt tape.

Return label: 4" x 4"

Instructional sheet: 5" x 7"

Paper Stock:

Package: 4mil white/ silver poly mailer with sequential identifier

Return label: 60# uncoated label stock Instructional sheet: 80# gloss text

Color:

Package: 5/3 print (silver, white, white, + 2 PMS on clear web; silver + 2 PMS on white web)

Return label: K/O no bleeds (personalized identifier)

Instructional sheet: K/K

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to requirements in the Ordinance.

Appendix H

Sample Injector Mail-Back Package



Description:

Injector Mail-Back Package including container with mail-back package, return label, and instructional flyer, and unique identifier enabling tracking at collection and disposal

Package Size:

1.4-quart mail-back system

Injector Mail-Back Package solutions are an example of complete, turnkey systems to provide for the safe return of Pre-filled Injector Products through the United States Postal Service. Injector Mail-Back Package solutions are tested and permitted to USPS specifications as outlined in USPS Publication 52.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to requirements in the Ordinance.

Appendix I

A. Sample Pureway Inhaler Mail-Back Package Specifications



Rx Waste Systems

For Inhaler Waste Only

WARNING

DO NOT dispose of any Non-Conforming Waste in this container.

Examples of Non-Conforming Waste include:

• Regulated Medical Waste

Aerosols w/more than 19.3oz

- Controlled Substances
- Mercury Devices

Live Vaccines

- Biohazardous Waste
- Sharps
- IV Bags

Please refer to the enclosed "Instructions For Use" for additional definitions and examples of Non-Conforming Waste

Description:

Inhaler Mail-Back Package including container with mail-back package, return label, and instructional flyer.

Package Sizes:

2.5-gallon mail-back system

Mail-back solutions are an example of complete, turnkey systems to provide for the safe return of inhaler waste through Carrier.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to the requirements in the Ordinance.

This postage paid shipment MUST be in this provided envelope. Any other packaging will be rejected. 8.75" 11.25"

B. Sample Stericycle Inhaler Mail-Back Package

Description:

Inhaler Mail-Back Package including container with mail-back packaging, return label, and instructional flyer.

Package Sizes:

Outer dimensions: 8.75"x 11.25"x 3"

Mail-back solutions are an example of complete, turnkey systems to provide for the safe return of inhaler waste through Shipper.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, subject to the requirements in the Ordinance.

Appendix J

Request for Approval of Standard Mail-Back Package Disposal Process

 $\begin{array}{c} \textbf{MED-PROJECT REQUEST FOR APPROVAL OF STANDARD MAIL-BACK PACKAGE DISPOSAL} \\ \textbf{PROCESS} \end{array}$



Medication Education & Disposal

April 15, 2019

MED-PROJECT REQUEST FOR APPROVAL OF STANDARD MAIL-BACK PACKAGE DISPOSAL PROCESS

Pursuant to § 4.116.110(f) of the County of San Mateo Safe Medicine Disposal Ordinance, Ordinance No. 04636, codified at Chapter 4.116 of Title 4 of the San Mateo County Ordinance Code ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Environmental Health Division (the "Director") to use permitted municipal waste combustors for the disposal of Standard Mail-Back Packages for unwanted medicine (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, because cost, logistics, and other considerations make disposal of Standard Mail-Back Packages at permitted hazardous waste facilities not feasible at this time, the Director should approve the disposal of Standard Mail-Back Packages at permitted municipal waste combustors under Ordinance § 4.116.070(b).Further, exercising discretion to allow for the disposal of mail-back packages at permitted municipal waste combustors would achieve the objectives of the Ordinance in accordance with § 4.116.110(f) of the Ordinance.

The use of a medical waste incinerator in Warren, Ohio, to dispose of Standard Mail-Back Packages was already approved by the Director on July 3, 2018. MED-Project is proposing these permitted municipal waste combustors as additional options for the disposal of Standard Mail-Back Packages.

I. THE PROCESS FOR THE DISPOSAL OF MAIL-BACK PACKAGES

To provide effective and uninterrupted "Standard Mail-Back Services" (as defined in Plan § III), MED-Project proposes to use Covanta Environmental Solutions, LLC ("Covanta") to provide and dispose of Standard Mail-Back Packages. Standard Mail-Back Packages provided by Covanta would be pre-addressed and pre-paid for delivery to the Covanta Manheim, Pennsylvania DEA registered collector and reverse distributor facility ("Manheim Facility"). From the Manheim Facility, the mail-back packages are transported by Doncin Transport, Inc. to the Covanta Lancaster, Inc. facility in Lancaster, Pennsylvania ("Covanta Lancaster") for destruction via incineration. *See* Plan § X. Covanta Lancaster will scan the unique identifier on each Standard Mail-Back Package to record receipt of the package before incinerating it and will confirm the materials have been properly incinerated.

Covanta Lancaster is a permitted large municipal waste combustor. Covanta Lancaster is an "energy-from-waste" facility that incinerates waste and generates 35.7 megawatts per day from a condensing steam turbine that provides energy to GPU Energy.² Covanta Lancaster employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a furnace dry-lime injection system, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. Covanta Lancaster operates under a Title V Clean Air Act permit³ and a solid waste permit.⁴ Covanta Lancaster is a "zero discharge" facility, meaning that the wastewater generated on-site is treated and reused in the waste management process, according to the facility's website. Covanta Lancaster has been designated as a Voluntary Protection Program ("VPP") Star facility by the U.S. Occupational Safety and Health Administration ("OSHA"), recognizing the facility's employer's and employees' exemplary achievement in the prevention and control of occupational safety and health hazards.

 ${}^2\textit{See}\ Covanta, Covanta\ Lancaster, \underline{https://www.covanta.com/Our-Facilities/Covanta-Lancaster.}$

¹ Covanta Lancaster's mailing address is 1911 River Road, Bainbridge, PA 17502.

³ See Title V Operating Permit # 36-05013, http://files.dep.state.pa.us/Air/AirQuality/AQPortalFiles/Permits/PermitDocuments/1130890[36-05013] Issued v1.pdf.

⁴ See Solid Waste Permit # 400592 PaDEP, https://www.ahs.dep.pa.gov/eFACTSWeb/searchResults_singleFacility.aspx?FacilityID=255039.

II. STANDARDS FOR THE DIRECTOR TO APPROVE THE USE OF THE PROPOSED INCINERATORS FOR THE DISPOSAL OF STANDARD MAIL-BACK PACKAGES

Under the Ordinance § 4.116.070(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including those collected in Standard Mail-Back Packages, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

Additionally, in approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance under § 4.116.110(f) in order to achieve the objectives of the Ordinance, which include protecting the environment and human health. *See*, *e.g.*, Ordinance § 4.116.070.

III. THE USE OF COVANTA LANCASTER TO DISPOSE OF STANDARD MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.070(B) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project requests approval to use the Covanta Lancaster municipal waste combustor because disposal of Standard Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project has worked with its vendors for Standard Mail-Back Packages to evaluate whether disposal at a hazardous waste disposal facility would be logistically feasible for Standard Mail-Back Packages collected under the Plan. The vendors have an established network of logistics and disposal companies, and at present, the use of a hazardous waste disposal facility is not logistically feasible, given the information MED-Project has received from its vendors about their access to treatment and disposal facilities.

Second, the cost to dispose of Standard Mail-Back Packages at a hazardous waste disposal facility, if any DEA-registered collector hazardous waste disposal facilities exist, would be much greater than the cost to dispose of such packages at the proposed incinerators. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than municipal waste combustors to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing and able to accept Standard Mail-Back Packages, if any such facilities exist, would cause delay and increase MED-Project's costs, further supporting the conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Standard Mail-Back Packages at a hazardous waste incinerator.

Third, there are no other laws or requirements, outside of the Ordinance, that would require MED-Project to dispose of Standard Mail-Back Packages at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a permitted municipal waste combustor. Any unwanted medicines collected via Standard Mail-Back Packages under this Plan are not regulated under California's hazardous waste regulations, and therefore are not required to be treated as hazardous waste. In fact, municipal waste combustors are one of the disposal methods that the U.S. Environmental Protection Agency directs law enforcement agencies to use for the destruction of collected pharmaceutical products. *See* U.S. Environmental Protection Agency, Management of Household Pharmaceuticals Collected by Law Enforcement During Take-Back Events and Programs at 2, 4 (Sept. 11, 2018).

For the above reasons, the Director should approve MED-Project's request to use Covanta Lancaster to dispose of Standard Mail-Back Packages under Ordinance § 4.116.070(b).

IV. THE USE OF THE PROPOSED INCINERATOR TO DISPOSE OF STANDARD MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE §§ 4.116.110(F) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

In the alternative, the Director should exercise its discretion and approve the use of the proposed incinerator for disposal of Standard Mail-Back Packages under Ordinance § 4.116.110(f) because disposal at this incinerator would protect the environment and human health in furtherance of the objectives of the Ordinance.

Disposal of Standard Mail-Back Packages at Covanta Lancaster would protect the environment and human health. Covanta Lancaster has extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. It has also been recognized for its workplace safety achievements, as evidenced by its status as a VPP Star facility.

As these applicable requirements and measures protect the environment and human health, the Director should exercise its discretion under Ordinance § 4.116.110(f) to approve Covanta Lancaster as the disposal site for Standard Mail-Back Packages.

V. CONCLUSION

Accordingly, the Director should approve the disposal of Standard Mail-Back Packages via incineration at Covanta Lancaster as proposed by MED-Project under Ordinance §§ 4.116.070(b) and 4.116.110(f).

Appendix K

Request for Approval of Injector Mail-Back Package Disposal Process

MED-PROJECT REQUEST FOR APPROVAL OF INJECTOR MAIL-BACK PACKAGE DISPOSAL PROCESS



April 15, 2019

MED-PROJECT REQUEST FOR APPROVAL OF INJECTOR MAIL-BACK PACKAGE DISPOSAL PROCESS

Pursuant to § 4.116.110(f) and § 4.116.070(b) of the County of San Mateo Safe Medicine Disposal Ordinance, San Mateo County Ordinance Code 4.116.010 – 4.116.190 ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Environmental Health Division (the "Director") to use a permitted medical waste incinerator for the disposal of Injector Mail-Back Packages (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, exercising discretion to allow for the disposal of Injector Mail-Back Packages at a permitted municipal waste combustor or medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 4.116.110(f) of the Ordinance. Further, because cost, logistics, and other considerations make disposal of Injector Mail-Back Packages at a permitted hazardous waste facilities not feasible at this time, approving the disposal of Injector Mail-Back Packages at a permitted medical waste incinerator would be consistent with the intent of Ordinance § 4.116.070(b).

I. THE PROCESS FOR THE DISPOSAL OF INJECTOR MAIL-BACK PACKAGES AT THE CURTIS BAY FACILITY

MED-Project intends to rely on PureWay Compliance, Inc. ("PureWay") as its vendor to provide Injector Mail-Back Packages and services. MED-Project is proposing that Injector Mail-Back Packages will be pre-addressed and prepaid for delivery to the Curtis Bay Energy, L.P. facility (the "Curtis Bay Facility"). The Curtis Bay Facility will scan the unique identifier on each Injector Mail-Back Package to record receipt of the package before incinerating it. The Curtis Bay Facility will provide confirmation that the materials have been properly incinerated and disposed of.

The Curtis Bay Facility is a permitted hospital, medical, and infectious waste incinerator. The Curtis Bay Facility operates two incineration units that are permitted to incinerate a maximum of 150 tons of waste per day for the facility. The Curtis Bay Facility operates under a Clean Air Act Title V permit, and is subject to emissions limits for a number of air pollutants in accordance with this permit. To control air pollution, the facility employs a tertiary combustion chamber, a dry injection acid gas scrubber, a powder activated carbon system, and a fabric filter with passive dioxins/furans emissions control.² The facility relies on a continuous opacity monitoring system and a continuous emission monitoring system for monitoring carbon monoxide, oxygen, and hydrogen chloride content levels of the stack exhaust gases.³ The Curtis Bay Facility also operates under an Industrial Wastewater Discharge Permit and Solid Waste Permit.

II. STANDARDS FOR THE DIRECTOR TO APPROVE THE USE OF THE PROPOSED INCINERATORS FOR THE DISPOSAL OF INJECTOR MAIL-BACK PACKAGES

Under the Ordinance § 4.116.070(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including injectors, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

Additionally, in approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance in order to achieve the objectives of the Ordinance to protect public health and the environment. § 4.116.110(f). Therefore, Ordinance § 4.116.110(f) grants the Director discretion to waive strict compliance with the disposal provision at § 4.116.070(a) requiring that collected covered drugs be disposed of at a permitted hazardous waste disposal facility.

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¹ Curtis Bay's mailing address is 3200 Hawkins Point Road, Baltimore, MD 21226.

² This information is drawn from the Curtis Bay Facility's Title V permit, http://www.mde.state.md.us/programs/Permits/AirManagementPermits/Test/Curtis%20Bay%20Energy.pdf.

³ Id.

III. THE USE OF THE PROPOSED INCINERATOR TO DISPOSE OF INJECTOR MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.110(F) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of the proposed incinerator for disposal of Injector Mail-Back Packages under Ordinance § 4.116.110(f) because disposal at the proposed incinerator would protect public health and the environment in furtherance of the objectives of the Ordinance. Furthermore, as explained below, the Director should also exercise its discretion to approve this alternative incineration method since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations.

The Director should also exercise its discretion to approve the use of the Curtis Bay Facility to dispose of Injector Mail-Back Packages since disposal at the Curtis Bay Facility is protective of the environment and would protect public health and the environment. The Curtis Bay Facility, as a medical waste incinerator, is subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The Curtis Bay Facility is subject to a range of environmental permits, including a Clean Air Act Title V permit for air emissions, an Industrial Wastewater Discharge Permit, and a Solid Waste Permit. The facility employs extensive air pollution controls and monitoring systems, including a tertiary combustion chamber, a dry injection acid gas scrubber, a powder activated carbon system, a fabric filter with passive dioxins/furans emissions control, and a continuous opacity monitoring system and continuous emission monitoring system. Additionally, facilities that handle medical waste, like the Curtis Bay Facility, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures. As these requirements protect public health and the environment, the Director should exercise its discretion under Ordinance § 4.116.110(f) to approve the Curtis Bay Facility as a disposal site for Injector Mail-Back Packages.

IV. THE USE OF THE PROPOSED INCINERATOR TO DISPOSE OF INJECTOR MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.070(B) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project proposes to use the Curtis Bay Facility because disposal of Injector Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project has worked with its vendor for Injector Mail-Back Packages to evaluate whether disposal at a hazardous waste disposal facility would be logistically feasible for Injector Mail-Back Packages collected under the Plan. The vendor has an established network of logistics and disposal companies, and at present, the use of a hazardous waste disposal facility is not logistically feasible, given the information MED-Project has received from its vendor about the vendor's access to treatment and disposal facilities.

Second, the cost to dispose of Injector Mail-Back Packages at a hazardous waste disposal facility would be much greater than the cost to dispose of such packages at the proposed facility. In MED-Project's experience, hazardous waste incinerators charge significantly more than other facilities to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing to accept Injector Mail-Back Packages and ensuring that MED-Project's vendor is capable of delivering Injector Mail-Back Packages to that facility would cause delay in service to the public and increase MED-Project's costs, further supporting the conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Injector Mail-Back Packages at a hazardous waste incinerator.

Third, there are no other laws or requirements, outside of the Ordinance, that would require MED-Project to dispose of Injector Mail-Back Packages at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a municipal waste combustor or medical waste incinerator. The California Medical Waste Management Act expressly includes "incineration" as one of the options for rendering sharps waste noninfectious prior to disposal. Cal. Health & Safety Code § 118225(a)(1). Any injectors collected by MED-Project under this Plan are not regulated under California's hazardous waste regulations, and therefore are not required to be treated as hazardous waste.

For the above reasons, the Director should approve MED-Project's request to use the Curtis Bay Facility pursuant to Ordinance § 4.116.110(f) and consistent with Ordinance § 4.116.070(b).

V. CONCLUSION

Accordingly, the Director should approve the disposal of Injector Mail-Back Packages via incineration at the Curtis Bay Facility as proposed by MED-Project under Ordinance § 4.116.110(f) and consistent with Ordinance § 4.116.070(b).

Appendix L

Request for Approval of Inhaler Mail-Back Package Disposal Process

MED-PROJECT REQUEST FOR APPROVAL OF INHALER MAIL-BACK PACKAGE DISPOSAL PROCESS



Medication Education & Disposal

April 15, 2019

MED-PROJECT REQUEST FOR APPROVAL OF INHALER MAIL-BACK PACKAGE DISPOSAL PROCESS

Pursuant to § 4.116.110(f) and § 4.116.070(b) of the County of San Mateo Safe Medicine Disposal Ordinance, San Mateo County Ordinance Code 4.116.010 – 4.116.190 ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Environmental Health Division (the "Director") to use permitted municipal waste combustors and a permitted medical waste incinerator for the disposal of Inhaler Mail-Back Packages (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, exercising discretion to allow for the disposal of Inhaler Mail-Back Packages at a permitted municipal waste combustor or permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 4.116.110(f) of the Ordinance. Further, cost, logistics, and other considerations make disposal of Inhaler Mail-Back Packages at permitted hazardous waste facilities not feasible at this time.

I. THE PROCESSES FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES AT THE PROPOSED INCINERATORS

MED-Project has identified two vendors that it may use to provide and dispose of Inhaler Mail-Back Packages. The two vendors are PureWay Compliance, Inc. ("PureWay") and Stericycle, Inc. ("Stericycle"). Each vendor has a slightly different disposal process, as laid out below.

A. <u>Pureway's Process</u>

MED-Project is proposing that one vendor for Inhaler Mail-Back Packages will PureWay. The Inhaler Mail-Back Packages provided by PureWay be pre-addressed and pre-paid for delivery to a transfer facility for transport to one of three incinerators for disposal: the Covanta Huntsville, Inc. facility (the "Covanta Huntsville Facility")¹; the Covanta Marion, Inc. facility (the "Covanta Marion Facility")²; or the Healthcare Environmental Services, LLC's Fargo Facility (the "HESI Facility").³ The transfer facility will scan the unique identifier on each Inhaler Mail-Back Package to record receipt of the package before sending it for incineration to one of these three facilities. These facilities will receive and dispose of the Inhaler Mail-Back Packages and provide confirmation that the materials have been properly incinerated and disposed of.

Two of the facilities – the Covanta Huntsville Facility and the Covanta Marion Facility – are permitted municipal waste combustors. The HESI Facility is a permitted medical waste incinerator.

B. Covanta Huntsville Facility

The Covanta Huntsville Facility is a permitted large municipal waste combustor. The furnaces at the Covanta Huntsville Facility are operated at temperatures exceeding 1800 degrees Fahrenheit. As a "waste-to-energy" facility, the Covanta Huntsville Facility uses municipal solid waste, like Inhaler Mail-Back Packages, to generate steam used for the U.S. Army's nearby Redstone Arsenal's heating and air conditioning needs. To control air pollution, the Covanta Huntsville Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. Additionally, the Covanta Huntsville Facility has been designated as a Voluntary Protection Program ("VPP") Star facility by the U.S. Occupational Safety and Health Administration ("OSHA"), recognizing the facility's employer's and employees' exemplary achievement in the prevention and control of occupational safety and health hazards.

¹ Covanta Huntsville's mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.

² Covanta Marion's mailing address is 4850 Brooklake Road, NE, Brooks, OR 97305.

³ The HESI Facility's mailing address is 1420 40th Street North, Fargo, ND 58102.

⁴ See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, http://swdahsv.org/waste-to-energy/.

⁵ See Covanta, Covanta Huntsville, https://www.covanta.com/Our-Facilities/Covanta-Huntsville.

⁶ Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

C. Covanta Marion Facility

The Covanta Marion Facility is also a permitted large municipal waste combustor. The Covanta Marion Facility is a "waste-to-energy" facility that incinerates waste and generates 13.1 megawatts per day from a condensing steam turbine generator that provides energy to the local utility. Like the Covanta Huntsville Facility, the Covanta Marion Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system.⁸ The Covanta Marion Facility is a member of the Safety and Health Achievement Recognition Program ("SHARP"), Oregon's safety and health recognition program.⁹ The Covanta Marion Facility has also been designated as a VPP Star facility by OSHA.¹⁰

D. Stericycle's Process

MED-Project is proposing that the other vendor for Inhaler Mail-Back Packages will be Stericycle. The Inhaler Mail-Back Packages provided by Stericycle will be pre-addressed and pre-paid for delivery to the Stericycle incinerator in Warren, Ohio (the "Warren Incinerator")¹¹ for incineration. The Warren incinerator will scan the unique identifier on each Inhaler Mail-Back Package to record receipt of the package and will confirm the materials have been properly incinerated and disposed of.

Warren Incinerator

The Warren Incinerator is a permitted hospital, medical, and infectious waste incinerator. The incinerator's primary chamber has a minimum exit gas temperature of 1400 °F, and the incinerator's secondary chamber is operated at over 1,830.5 °F. The Warren Incinerator has a Clean Air Act Title V permit, which establishes air emissions limits for particulate matter, carbon monoxide, dioxins/furans, hydrogen chloride, sulfur dioxide, nitrogen oxides, lead, cadmium, and mercury, among other chemicals. To control air pollution, the Warren Incinerator employs a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system, among other controls. The incinerator stack must be designed to minimize the impact of emissions on employees, residents, visitors, and nearby residences.

STANDARDS FOR THE DIRECTOR TO APPROVE THE USE OF THE PROPOSED II. INCINERATORS FOR THE DISPOSAL OF INHALER MAIL-BACK PACKAGES

In approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance under § 4.116.110(f) in order to achieve the objectives of the Ordinance to protect public health and the environment. Therefore, Ordinance § 4.116.110(f) grants the Director discretion to waive strict compliance with the disposal provisions at § 4.116.070 requiring that such materials be disposed of at a permitted hazardous waste disposal facility.

Additionally, under the Ordinance § 4.116.070(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including inhalers, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

⁷ See Covanta, Covanta Marion, https://www.covanta.com/Our-Facilities/Covanta-Marion.

¹⁰ Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

¹¹ The Warren Facility's mailing address is 1901 Pine Ave SE, Warren, OH 44483.

III. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.110(F) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of all three proposed incinerators for disposal of Inhaler Mail-Back Packages under Ordinance § 4.116.110(f) because disposal at the proposed incinerators would protect public health and the environment, as discussed further below, in furtherance of the objectives of the Ordinance. Furthermore, as explained in section IV below, the Director should also exercise its discretion to approve these alternative incineration methods since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations.

A. Covanta Huntsville and Covanta Marion Facilities

Disposal of Inhaler Mail-Back Packages at the Covanta Huntsville Facility and Covanta Marion Facility would provide for and protect the health, safety, and welfare of the general public. In particular, these facilities have extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. They have also been recognized for their workplace safety achievements, as evidenced by their status as VPP Star facilities.

B. Warren Incinerator

Disposal of Inhaler Mail-Back Packages at the Warren Incinerator would also provide for and promote the health, safety, and welfare of the general public, like the municipal waste combustors. Medical waste incinerators, like the Warren Incinerator, are typically subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The Warren Incinerator is subject to environmental permits, including a Clean Air Act Title V permit for air emissions and a state solid waste management permit, and the facility has extensive air pollution controls in place, including a carbon bed system, continuous emissions monitoring systems, a selective non-catalytic reduction system, and a scrubber system. The facility's Title V air permit cites to federal standards and emissions limits that are specific to incinerators for hospital, medical, and infectious waste. Additionally, facilities that handle medical waste, like the Warren Incinerator, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

Finally, the Director should also exercise its discretion under Ordinance § 4.116.070(b) to approve the Warren Incinerator since disposal at a hazardous waste facility is not feasible at this time due to logistics, cost, and other considerations, as described in the following section IV.

IV. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 4.116.070(B) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

MED-Project proposes to use the Covanta Huntsville Facility and the Covanta Marion Facility because disposal of Inhaler Mail-Back Packages at permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project engaged multiple potential vendors to evaluate whether they could distribute, receive, and dispose of Inhaler Mail-Back Packages, but most vendors do not offer such services. Furthermore, the vendors who offered these services for Inhaler Mail-Back Packages, PureWay and Stericycle, only offer disposal at municipal waste combustors (the Covanta Huntsville Facility and the Covanta Marion Facility) and a medical waste incinerator (the Warren Incinerator), respectively. Accordingly, the use of a hazardous waste disposal facility for Inhaler Mail-Back Packages is not logistically feasible at present, given the information MED-Project has received from its vendors about the vendors' access to disposal facilities.

Second, the cost to dispose of Inhaler Mail-Back Packages at a hazardous waste disposal facility would be much greater than the cost to dispose of such packages at the proposed facilities. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than other facilities to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing to accept Inhaler Mail-Back Packages and ensuring that one of MED-Project's vendors is capable of delivering Inhaler Mail-Back Packages to that facility would cause delay in service to the public and increase MED-Project's costs, further supporting the conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Inhaler Mail-Back Packages at a hazardous waste incinerator.

Third, there are no other laws or requirements, outside of this Ordinance, that would require MED-Project to dispose of Inhaler Mail-Back Packages at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a municipal waste combustor or medical waste incinerator. Any inhalers collected by MED-Project under this Plan are not regulated under the California's hazardous waste regulations, and therefore are not required to be treated as hazardous waste.

For the above reasons, the Director should approve MED-Project's request to use the Covanta Huntsville Facility and Covanta Marion Facility to dispose of Inhaler Mail-Back Packages under Ordinance § 4.116.070(b), which authorizes the Director to approve disposal at a municipal waste combustor.

Additionally, the use of the Warren to dispose of Inhaler Mail-Back Packages would meet the same standard. Disposal at the Warren Incinerator is at least as protective of the environment and human health, as compared to a municipal waste combustor. *See* sections II and III above. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 4.116.070(b), but not at a medical waste facility (i.e., the Warren Incinerator) that would provide for and promote the health, safety, and welfare of the general public. Accordingly, MED-Project requests that the Director approve disposal of Inhaler Mail-Back Packages at the Warren Incinerator.

V. CONCLUSION

Accordingly, the Director should approve the disposal of Inhaler Mail-Back Packages via incineration at the Covanta Huntsville Facility, the Covanta Marion Facility, and the Warren Incinerator as proposed by MED-Project under Ordinance § 4.116.110(f) and § 4.116.070(b).

Appendix M

Stericycle, Inc., Indianapolis, Indiana Facility Penalty Record

Date	Туре	Summary	Violation Detail	Return to Compliance	Corrective Action
6/15/2017	RCRA	Inventory weight discrepancy	Discrepancy on the haz waste inventory log	6/15/2017	Violation corrected during audit, no further action required
3/29/2017	RCRA	Inventory weight discrepancy	Discrepancy on the haz waste inventory log	3/29/2017	Violation corrected during audit, no further action required
3/29/2017	RCRA	Hazardous waste labeling	Containers missing date	3/29/2017	Violation corrected during audit, no further action required
7/25/2016	RCRA	Inventory dates	Inventory dates and physical dates on containers did not match	10/25/2016	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter
7/17/2015	RCRA	Hazardous waste labeling	Unlabeled universal waste pallets	11/17/2015	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter
7/17/2015	RCRA	Contingency Plan	Contingency Plan list of emergency coordinators not updated with current contact information	11/17/2015	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter

Date	Туре	Summary	Violation Detail	Return to Compliance	Corrective Action
7/31/2014	RCRA	Inventory weight discrepancy	Discrepancies regarding the quantity (weight) of waste stored in permitted areas compared to the weights listed on the physical containers	9/8/2014	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter
6/5/2014	Air	Annual report not submitted	Did not submit Annual Compliance Certification for period covering 1/1/13 to 12/31/13	6/9/2014	Report submitted to IDEM; issue closed with Return to Compliance Letter
3/26/2014	RCRA	Satellite Accumulation violation	Two containers exceeded the 3-day limit for moving satellite accumulation area to the container storage area	6/17/2014	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter
3/26/2014	RCRA	Inventory weight discrepancy	Discrepancies regarding the quantity (weight) of waste stored in permitted areas compared to the weights listed on the physical containers	6/17/2014	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter

Date	Туре	Summary	Violation Detail	Return to Compliance	Corrective Action
3/26/2014	RCRA	Container storage	One container of hazardous waste located outside of the permitted area	6/17/2014	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter
6/28/2013	RCRA	Satellite Accumulation/Waste Accumulation Labeling; Inventory Log discrepancy	Missing satellite accumulation and UW label; Missing Accumulation Date and Waste Type; Discrepancy on container storage locations	10/16/2013	Responded to IDEM with corrective action plan; issue closed with Return to Compliance Letter

Veolia – Port Arthur Penalty Record

Inspection Date	Type of inspection	Name of inspector and Regulatory Agency	Alleged Violations	VEOLIA Responses and/or Corrective Actions Taken
3/9/2017	CAA	Texas Commission on Environmental Quality ("TCEQ")	 Failure to maintain the Carbon Monoxide emission rate of 17.10 pounds per hour at the incinerator. Failure to maintain Carbon Monoxide emissions of 100 parts per million by volume (ppmv) at the incinerator. Failure to maintain incinerator minimum combustion temperatures. Failure to maintain Arsenic and Chromium emission rates at the Incinerator. Failure to maintain combined Cadmium-Lead and combined Arsenic-Beryllium-Chromium emissions at the Incinerator. Failure to maintain the Carbon Monoxide emission rate of 17.10 pounds per hour during start-up at the Incinerator. 	4/18/2017: Received NOV. 5/27/2017: Submitted Corrective Action Plan. 9/29/2017: Received a letter from the TCEQ stating adequate compliance documentation was received and no further action required.

Inspection Date	Type of inspection	Name of inspector and Regulatory Agency	Alleged Violations	VEOLIA Responses and/or Corrective Actions Taken
5/16/2016	RCRA	TCEQ	 Failure to maintain hazardous waste tanks inspection records. Failure to maintain a current NOR status of INACTIVE for hazardous waste tanks inspection records. Failure to include on the emergency equipment list, One Self Contained Breathing Apparatus (SCBA) located at the onsite Response Office. Failure to have legible posted signs with the legend Danger-Unauthorized Personnel Keep Out. Failure to have adequate security to prevent unknowing site entry. 	7/26/2016: Received NOV. 8/25/2016: Submitted Corrective Action Response. 3/1/2017: Received a letter from the TCEQ stating no further action required.

Inspection Date	Type of inspection	Name of inspector and Regulatory Agency	Alleged Violations	VEOLIA Responses and/or Corrective Actions Taken
1/26/2016	CAA Title V/NSR Air	TCEQ	 Failure to maintain the Carbon Monoxide emission rate of 17.10 pounds per hour at the Incinerator. Failure to maintain Carbon Monoxide emissions of 100 parts per million by volume (ppmv) at the Incinerator. Failure to maintain Incinerator minimum combustion temperatures. Failure to maintain Arsenic, Beryllium, Cadmium, Chromium and Nickel emission rates at the Incinerator. Failure to maintain combined Cadmium-Lead and combined Arsenic-Beryllium-Chromium emissions at the Incinerator. Failure to prevent visible emissions at Tank T102. Failure to make a first attempt at repair no later than 5 days after a leak is detected and failed to repair a leak no later than 15 days after a leak is detected. 	4/27/2016: Received NOV from the TCEQ 6/3/2016: Submitted a response to the TCEQ. 9/20/2016: Received a letter from the TCEQ stating no further action required.
4/22/2015	TPDES	TCEQ	 Failure to collect ammonia-nitrogen sample at the frequency specified in the Water Quality Discharge Permit for Outfall 001. Failure to comply with test procedures specified in 30 TAC 319.11-319.12. Failure to properly calculate the daily average for E. coli. Failure to correctly report effluent data on the discharge monitoring report. 	5/20/2015: Submitted a response to TCEQ 6/10/2015: Received a letter from the TCEQ stating no further action is required.

Inspection Date	Type of inspection	Name of inspector and Regulatory Agency	Alleged Violations	VEOLIA Responses and/or Corrective Actions Taken
1/30/2015	Drinking Water	TCEQ	Received NOV for failure to Provide or Report Public Notice.	2/20/2015: Submitted a response to TCEQ. 12/31/2015: No further correspondence received.
1/16/2015	Drinking Water	TCEQ	 Failure to have an accurate and up to date plant operations manual. Failure to inspect the interior of the 5,000-gallon pressure tank at least once every 5 years. Failure to notify TCEQ prior to making any significant change or addition to the system's production, treatment, storage, pressure maintenance, or distribution facilities. Failure to record the amount of chemicals used at least once a week. 	5/29/2015: Submitted a response to TCEQ 7/30/2015: Received a request from the TCEQ for additional information. 11/3/2015: Submitted a response to TCEQ 12/30/2015: Received a letter from the TCEQ stating the drinking water project was approved.
1/6/2015	Air	TCEQ	Failure to maintain the Carbon Monoxide emission rate at the Incinerator. For the period of April 4, 2014 through August 18, 2014.	3/6/2015: Submitted a response to the TCEQ. 6/24/2015: Received a letter from TCEQ stating no further action is required.
11/3/2014	Drinking Water	TCEQ	Received an NOV for failure to submit Disinfectant Level Quarterly Operating Report.	
9/26/2014	RCRA	TCEQ	Failure to document inspector's full name on daily inspection logs. Failure to include a notation of the observations made during daily & weekly inspections	10/22/2014: Submitted Response to TCEQ. 2/9/2015: Received documentation stating no further action is required.

Inspection Date	Type of inspection	Name of inspector and Regulatory Agency	Alleged Violations	VEOLIA Responses and/or Corrective Actions Taken
2/20/2013	CAA	TCEQ	 Failure to maintain a minimum power of 15 Kilovolt Amps (KVA) to the Wet Electrostatic Precipitator (WESP) (EPN INCINSTK). Failure to conduct the 4th quarter Cylinder Gas Audits on the Hydrogen Chloride (HCI) and Sulfur Dioxide (SO2) CWMS. Failure to maintain carbon monoxide emission rate at the Incinerator (EPN INCINSTK). 	5/24/2013: Submitted Response to TCEQ for Alleged Violations 1. and 2. 6/21/2013: Received letter from the TCEQ stating no further action is required for Alleged Violations 1. and 2. 5/2/2013: Received Notice of Enforcement for Alleged Violation 3. 9/12/2013: Received Revised Proposed Agreed Order Assessing Penalty 9/16/2013: Submitted Payment of Penalty 2/20/2014: Received Final Agreed Order 3/25/2014: Submitted written certification and documents to demonstrate compliance. 8/22/2014: Received Notice of Compliance with Agreed Order

Heritage Thermal Services – Ohio Penalty Record

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
NOV	5/26/17		DAPC	HTS exceeded THC 1- hr rolling average on March 25, 2017 (Title V).	NA	Closed – OEPA issued resolution of violation letter on 7/11/17.
NOV	2/12/16		OSHA	Failure to ensure employee was wearing proper PPE.	\$27,720	Closed – HTS settled this matter on October 14, 2016.
NOV	1/21/16		DAPC	HTS exceeded NOx 3hr block average on June 28, 2015 (Title V).	NA	Closed - NOV resolved in letter dated 02/25/16; HTS responded with action plan in a letter dated February 5, 2016.
Director's Final Findings & Orders	4/2/2015	1250 Saint George Street East Liverpool, Ohio, 43920	Ohio EPA ("OEPA"), Ohio Division of Air Pollution Control ("DAPC") and Ohio Division of Materials and Waste Management ("DMWM")	Notices of violation ("NOVs") issued to HTS due to the 7/13/13 Incident: Dust Nuisance (DAPC) Unlawful disposal of hazardous waste and improper maintenance and operation of equipment (DMWM)	\$34,000	Heritage Thermal Services ("HTS") is in discussions with Ohio EPA

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
Finding of Violation	3/25/2015	1250 Saint George Street East Liverpool, Ohio, 43920	US EPA	HTS exceeded Maximum Achievable Control Technology ("MACT") standard and Title V Operating Parameter Limits on several occasions.	TBD	HTS is in discussions with US EPA
NOV	9/16/2014	1250 Saint George Street East Liverpool, Ohio, 43920	DMWM	Violation of Ohio Administrative Code ("OAC") 3745-55-75(b) Bulk waste container stored outside of secondary containment.	NA	Closed – Return to compliance ("RTC") received in a letter dated December 8, 2014. September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.
NOV	9/16/2014	1250 Saint George Street East Liverpool, Ohio, 43920	DMWM	Violation of OAC 3745-54-15(c) Immediate action had not been taken to prevent further incident following discovery of equipment damage.	NA	Closed – RTC received in a letter dated December 8, 2014, September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
NOV	9/16/2014	1250 Saint George Street East Liverpool, Ohio, 43920	DMWM	Violation of Permit Condition C.6(c) Spills not cleaned up in a timely manner.	NA	Closed – RTC received in a letter dated December 8, 2014, September 16, 2014 letter acknowledged that issue had been corrected on date of inspection.

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
NOV	10/2/2013	1250 Saint George Street East Liverpool, Ohio, 43920	DMWM	Ash release on 7/13/13 was an unlawful Disposal of Hazardous Waste. Failure of proper Operation and Maintenance of equipment/facility	NA	HTS responded in a letter dated October 21, 2013. HTS met with OEPA on 9/22/14 to provide update. HTS provided written update and request for RTC in letter dated 10/17/14. HTS 2 nd request for RTC in letter dated 12/12/14. HTS 3 rd request for RTC in letter dated 2/3/2015. HTS has completed requirements for RTC and is actively pushing OEPA for RTC.

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
NOV	8/5/13	1250 Saint George Street East Liverpool, Ohio, 43920	Ohio Division of Air Pollution Control ("DAPC")	Ash release determined to be a public nuisance in violation of OAC 3745-15-07	NA	HTS responded in a letter dated August 22, 2013. HTS met with OEPA on 9/22/14 to provide update. HTS provided written update and request for RTC in letter dated 10/17/14. HTS 2 nd request for RTC in letter dated 12/12/14. HTS 3 rd request for RTC in letter dated 12/12/14. HTS 3 rd request for RTC in letter dated 12/3/2015. HTS has completed requirements of RTC and is actively pushing OEPA for RTC.

Type of Action	Date	Address	Regulatory Body/Agency	Description of Alleged Violation	Fine Amount	Final Disposition
NOV	6/21/2013	1250 Saint George Street East Liverpool, Ohio, 43920	OSHA	Violation of various standards — decontamination, improper storage of water reactives, not identifying hazards.	\$11,802	Closed – HTS settled this matter on 8/30/13. HTS and OSHA met for informal conference on 7/16/13. Agreement reached – citation 4 vacated, instances a and c for citation 3 vacated; rewording of citation 1 and 2. Penalty reduced to \$11,802.

Clean Harbors Aragonite, LLC Enforcement Summary Fact Sheet

Clean Harbors Aragonite is subject to regulatory inspections by multiple agencies. While our goal is 100% compliance with all permits and regulatory requirements, inspections can result in alleged violations. This document is a summary from those inspections.

Although the company does not necessarily concur with these findings, consistent with the company's standard policy it has agreed to take all steps necessary to comply with the orders and to take such other corrective measures so as to ensure that the facility is in full compliance with its federal and state operating permits.

In 2015 the facility resolved a notice of violation with USDEA. Alleged violations are listed below followed by the *facility response in bold italicized text*.

- Failure to maintain a current license required by the state of Utah. A former compliance manager did not renew one of two state licenses. This was discovered during an internal audit and selfreported to both Utah and DEA. The facility voluntarily discontinued acceptance of controlled substances until the permit was obtained.
- 2. Failure to maintain separate biennial reports for Schedule I/II and III/IV/V controlled substances.

 The facility had zero inventory and reported that on one form. We disagreed with this allegation. If there was any inventory to report it would have been done on separate forms as required by the regulations.
- 3. Failure to maintain complete and accurate records. Information was contained on Form 41's as required by regulation but would not fit in the column DEA considered appropriate. The facility began to use revised DEA form 41's (that includes more space) to address the issue.

This was resolved by a consent order that included a \$63,000 penalty.

In 2015 the facility resolved a notice of violation with Utah Board of Pharmacy for the same issue as #1 above.

This was resolved by an administrative order that included a \$20,000 penalty.

In 2014 the facility resolved a notice of violation with USDEA. Alleged violations are listed below followed by the *facility response in bold italicized text*.

- 1. Failure to complete an accurate biennial inventory. The facility had zero inventory and reported that on a Clean Harbors letterhead. We disagreed with this violation. If there was any inventory to report it would have been done on forms as required by the regulations.
- 2. Failure to document the number of items received and the date items were received on a copy 3 of DEA form 222. This information was documented on a transfer form but not copied to a form 222. Facility personnel were retrained to address the issue.
- 3. Failure to execute a form 222 to transfer substances to another registered entity. A shipment count did not match and was rejected back to the generator. The facility did not include rejection using a form 222. Facility personnel were retrained to address the issue.
- 4. Failure to report the required documents in ARCOS in a complete and accurate manner. We disagreed with this violation. All reports were submitted to ARCOS. There were several errors not yet corrected at the time of the inspection. All errors were subsequently corrected.

This was resolved by a consent order that included a \$190,000 penalty.

In 2013 the facility resolved a notice of violation with UDEQ. This pertains to an annual RCRA inspection conducted in 2012. Alleged violations are listed below followed by the *facility response in bold italicized text*.

- The facility self-reported a permit condition to record times each backup carbon adsorber is used
 was not followed. During an internal audit it was discovered a PLC that records backup carbon
 usage was rounding minutes incorrectly and slightly underreported usage. The programming was
 corrected.
- 2. The facility self-reported that a water reactive labpack in excess of four liters was accepted and incinerated, in violation of permit conditions. The material is acceptable but not in excess of four liters per container. The person responsible for the mistake was disciplined.
- 3. UDEQ alledged that weekly emergency shower and eyewash inspections were not noted in inspection tags. We disagreed with this violation. Inspections were performed and documented on an inspection log.
- 4. UDEQ alleged that a leaking roof repair was not completed within 72 hours as required by permit. We disagreed with this violation. During a January storm, ice accumulated on a roof over Building E-2. Once it warmed above freezing a small leak was discovered. Due to the dangers of roofing contractors on frozen roofs, this was not repaired until May
- 5. UDEQ alleged the facility did not report a fire as required by the permit. We disagreed with this violation. Heat tracing under pipe insulation shorted arced and melted wire insulation. There was not a fire and as such was not reportable.
- 6. UDEQ alleged that a RCRA air subpart BB/CC database and associated drawings were not kept updated. The database was accurate but drawings were not current.
- 7. UDEA alleged that an incoming container tested positive for oxidizers and that container should have been reclassified as a DOT oxidizer. We disagreed with this violation. The container held mixed acids, some of which do test positive for oxidizers. This was not an oxidizer per DOT standards.
- **8.** The facility self-reported that an inbound trailer was not offloaded within 10 days as required by permit. **No comment. This was self-reported.**

This was resolved by a consent order that included a \$31,155 penalty.

In 2012 the facility resolved a notice of violation with UDEQ. This pertains to an annual RCRA inspection conducted in 2011. Alleged violations are listed below followed by the *facility response in bold italicized text*.

- 1. UDEQ alleged there was a calibration problem with the oxygen analyzer in the hydrocarbon vent system. We disagreed with this violation. The facility inspection program found and corrected the problem prior to the inspection. This was corrected by installing a condensation trap and filter prior to the analyzer.
- 2. The facility self-reported to UDEQ that the direct burn flow meter was incorrectly calibrated. *This was immediately corrected when discovered.*
- 3. UDEQ alleged the facility did not properly describe a waste being accepted on the waste receiving report. We disagreed with this violation. The waste was profiled with a range (IE: yellow liquid 0-25%) so the waste received description can seem subjective compared to the profile.
- **4.** UDEQ alleged 2 drums of site generated waste were incinerated without burn chemistry documentation. *The facility believes this was done but documentation could not be produced. Personnel involved were retrained.*
- 5. There were seven additional examples of improper burn chemistry documentation violations. To address the issues, the waste analysis plan was recently modified that will allow burn chemistry matrixes to be applied based on sampling and analysis of each waste stream. This information is documented in the operating record.
- 6. UDEQ alleged the facility did not properly completed inspection logs. *During this timeframe, a new* electronic inspection log was implemented. One day the log would indicate an issue and the next

- day it passed. The problem was attributed to a pop up warning that did not properly function. This was promptly corrected.
- 7. UDEQ alleged that crack repairs to a secondary containment system was a violation. We disagreed with this violation. The cracks were found during an inspection. They could not be repaired within 72 hours as required by permit due to weather. UDEQ was notified prior to 72 hours as required by the permit. The cracks were promptly repaired when the weather was dry and >50°F. (needed for the epoxy to cure)
- 8. UDEQ alleged the facility did not report a fire as required by the permit. We disagreed with this violation. A hose connected to a propane torch became disconnect causing an incidental fire. The permit requires any fire in an area where waste is managed to be reported. The fire did not meet reporting required by the permit.
- 9. UDEQ alleged an instrument calibration log was not signed by the technician who did the calibration. The person did not sign the log as required. He was retrained.

This was resolved by a consent order that included a \$35,017 penalty.

In 2012 EPA issued a warning letter alleging seven instances of TRI reporting errors from 2007 through 2010. *These mistakes were made by a former employee who is no longer employed by Clean Harbors.*

This was resolved by a consent order that included a \$39,900 penalty.

Questions associated with this fact sheet should be directed to Mike Crisenbery, VP Compliance (513-823-2280).

Curtis Bay Energy Penalty Record

Date	Туре	Summary	Detail	Fine Amount	Return to Compliance Date	Corrective Action
March 2015	Air	HCI Emissions failure was caused by incomplete Trona injection, CO Emissions failure was caused by incomplete combustion of the waste, and Opacity Emission. Failure was caused by bag malfunction	Hydrogen Chloride (HCI), Carbon Monoxide (CO), and opacity limit exceedance	fine amount \$125,000, settlement \$50,000	January 2016	 i. HCI Emissions failure was addressed Installation of a DSI (Dry Sorbent Injection System) ii. CO failure was addressed by implementing better engineering practices and installing a new conveyor system for providing enhanced blended for better emissions control. iii. Opacity Emissions Failure was corrected with ongoing preventive maintenance of the bags.

Appendix N

Sample Brochure and Mail-Back Inserts

Translations of the brochure will be available in the Required Languages.

Front of brochure

WHAT SHOULD YOU DO WITH **YOUR UNWANTED** OR EXPIRED MEDICINES?

Medication Education & Disposal

What should you do with your expired or



to dispose of expired or unwanted medicines.

www.med-project.org or call 1-844-MED-PROJECT unwanted medicines?



Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It's vitally important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It's also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

If you have expired or unwanted medication. proper disposal is easy. To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the following disposal options.

(Source: U.S. Food and Drug Administration)



This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.







For more information about Sharps disposal resources, please visit: www.smchealth.org/sharps



DISPOSAL OPTIONS

1 CHECK THE PACKAGE



If there are specific instructions for disposal on the label, package or package insert, please follow those instructions.

CONVENIENT LOCATIONS



To find the drop-off sites in your area, visit the Convenient Locations section of www.med-project.org.

What items can I dispose of at a kiosk?





ACCEPTED:

MEDICATIONS IN ANY DOSAGE FORM, EXCEPT FOR THOSE LISTED BELOW, IN THEIR ORIGINAL CONTAINER OR SEALED

*If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.



NOT ACCEPTED:

HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, MEDICAL DEVICES, BATTERIES, MERCURY-CONTAINING THERMOMETERS, SHARPS, AND ILLICIT DRUGS.

DISPOSAL OPTIONS



MAIL-BACK



Mail-Back Services for Unwanted Medicine, pre-filled Injector Products, and Inhalers may be available. Visit the mail-back section of www.med-project.org to order a Mail-Back Package.



For more information about Sharps disposal resources, please visit: www.smchealth.org/sharps



To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above. Front of insert

UNWANTED OR EXPIRED MEDICATIONS



ACCEPTED: Medications in any dosage form, except for those listed below, in their original container or sealed bag.*

* If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.

NOTE: The following items are not accepted in Unwanted Medicine Mail-Back Envelopes: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, inhalers, sharps, and illicit drugs.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

Front of insert

MAIL-BACK PACKAGE IS FOR

INHALERS

ACCEPTED: Inhalers



NOTE: Only place undamaged Inhalers in their original containers in the Inhaler Mail-Back Package. Inhaler Mail-Back Packages can only be used for Inhalers and cannot accept other types of items.

To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the disposal options listed above.

MAIL-BACK PACKAGE IS FOR

PRE-LOADED PRODUCTS CONTAINING A SHARP AND AUTO-INJECTORS



NOTE: Injector Mail-Back Packages can only be used for Pre-filled Injector Products and cannot accept other types of items.

MED-Project™

Medication Education & Disposal

DISPOSAL OPTIONS:

1 CHECK THE PACKAGE

If there are specific instructions for disposal on the label, package or package insert, please follow those instructions.

3 MAIL-BACK

Mail-back Services for Unwanted
Medicine, Pre-filled Injector Products,
and Inhalers may be available. Visit the
mail-back section of www.med-project.org
to order a mail-back package.

2 CONVENIENT LOCATIONS

To find the drop-off sites in your area, visit the Convenient Locations section of www.med-project.org. Mail-Back Distribution Locations may also be available in your area.

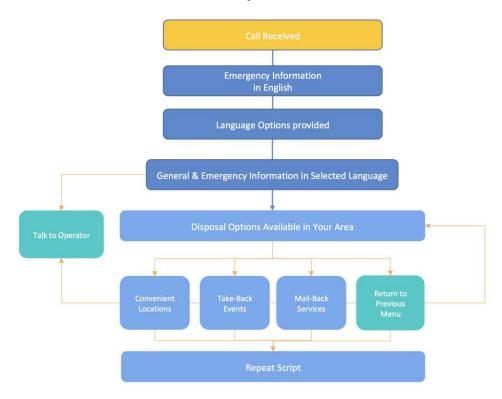
For more information about the MED-Project program, please go to www.med-project.org or call 1-844-MED-PROJECT.

Appendix O

Sample Call Center Script

MED-Project[™] Medication Education & Disposal

Thank you for calling the information line for the Medication Education and Disposal Project, or MED-Project.



Call Script:

- If you are experiencing a medical emergency, please hang up and dial 9-1-1.
- If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 800-222-1222.
- Unwanted Medicine Kiosks are located throughout your local area and provide convenient options for disposing of expired or Unwanted Medicine. <u>Press 3</u> for more information about convenient kiosks.
- Mail-Back Services are available to Residents. <u>Press 4</u> for more information.
- Take-back events may be scheduled throughout the year and offer Residents a free and convenient way to dispose of expired or Unwanted Medicine. Press 5 for more information.
- You may press 0 at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and consumer disposal.
- MED-Project reminds you that taking your medicine as directed by your health care provider is important to your health.

- If you have questions about your medication, please hang up and call your health care provider.
- For additional questions about the proper disposal of expired or unwanted medications from households, please go to MEDProject.org or press 0 to talk to an operator.
- To hear this menu again, please <u>press 1</u>.
- Thank you for calling MED-Project.

Unwanted Medicine Kiosk Script for when Option 3 Is Selected:

- Kiosks drop-off sites for Unwanted Medicine are located conveniently throughout your local area. To locate the site nearest you, or for precise information about hours of operation, <u>press 0</u> to speak with an operator or visit <u>MEDProject.org</u> to search by your zip code.
- Kiosks accept medications in any dosage form in their original container or sealed bag. Items that
 are not accepted include herbal remedies, vitamins, supplements, cosmetics or other personal
 care products; medical devices; batteries; mercury-containing thermometers; sharps; and illicit
 drugs.
- If you do transfer your medications to a sealed bag before placing it into a kiosk, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 3.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

Unwanted Medicine Mail-Back Services Script for when Option 4 is selected:

- Mail-Back Services for Unwanted Medicine and inhalers are available to Residents who are
 disabled and home-bound or home healthcare professionals providing services to disabled and
 home-bound Residents.
- Mail-Back Services are also available to all Residents for Pre-filled Injector Products.
- Unwanted Medicine Mail-Back Packages accept medications in any dosage form in their original
 container or sealed bag. Items that are not accepted include herbal remedies, vitamins,
 supplements, cosmetics or other personal care products; inhalers; medical devices; batteries;
 mercury-containing thermometers; sharps; or illicit drugs.
- To request a Mail-Back Package, please press 0 to talk to the operator or visit MEDProject.org.
- Mail-Back Distribution Locations may also be available in your area.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 4.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

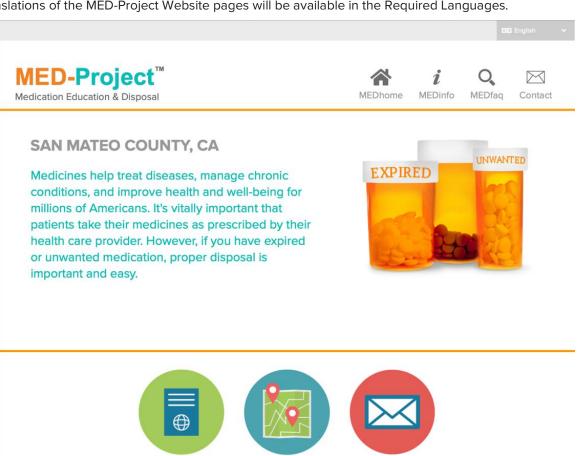
Unwanted Medicine Take-Back Event Script for when Option 5 is selected:

- MED-Project may be working with local law enforcement and other community organizations to
 offer regular expired and Unwanted Medicine take-back events in your area. For a complete list of
 take-back events, please <u>press 0</u> to speak to the operator, or visit <u>MEDProject.org</u>.
- Take Back Events accept medications in any dosage form in their original container or sealed bag.
 Items that are not accepted include herbal remedies, vitamins, supplements, cosmetics or other personal care products; medical devices; batteries; mercury-containing thermometers; sharps; and illicit drugs.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 5.
- To return to the main menu, please <u>press 1</u>.
- Thank you for calling MED-Project.

Appendix P

Sample MED-Project Website

Translations of the MED-Project Website pages will be available in the Required Languages.



CONVENIENT

LOCATIONS

MAIL **BACK**

CHECK THE

PACKAGE











CHECK THE PACKAGE

Follow any specific disposal instructions on the prescription drug labeling or patient information that accompanies the medicine. Do not flush medicines down the sink or toilet.

To protect your privacy, consumers are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

(Source: U.S. Food and Drug Administration)



CHECK THE PACKAGE

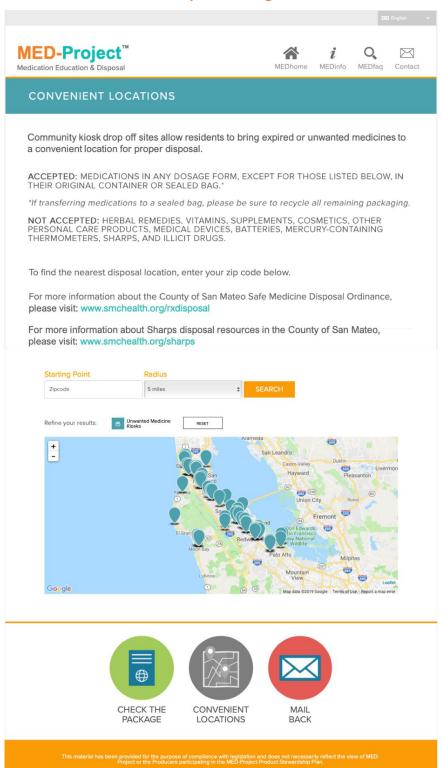


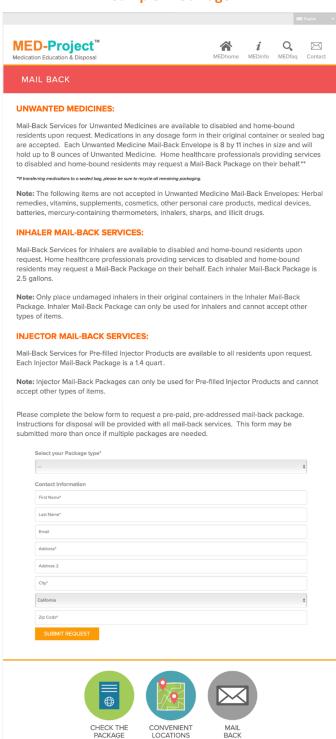
CONVENIENT LOCATIONS



MAIL BACK

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the view of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.





□□ English ✓











MEDinfo

Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It's vitally important that patients take their medicines as prescribed by their health care provider and as indicated on the label or packaging. It's also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

There are a number of ways to dispose of expired or unwanted medicines. To protect your privacy, consumers are reminded to remove all personally identifiable information on prescription labels or materials before using any of the available disposal options.

For additional information on the program, MED-Project has developed an educational toolkit, including: Brochure:

English Español Tagalog 中文

Disposal Location Flyers:

English Español Tagalog 中文

Frequently Asked Questions:

English Español Tagalog 中文

Radio Public Service Announcement (PSA):

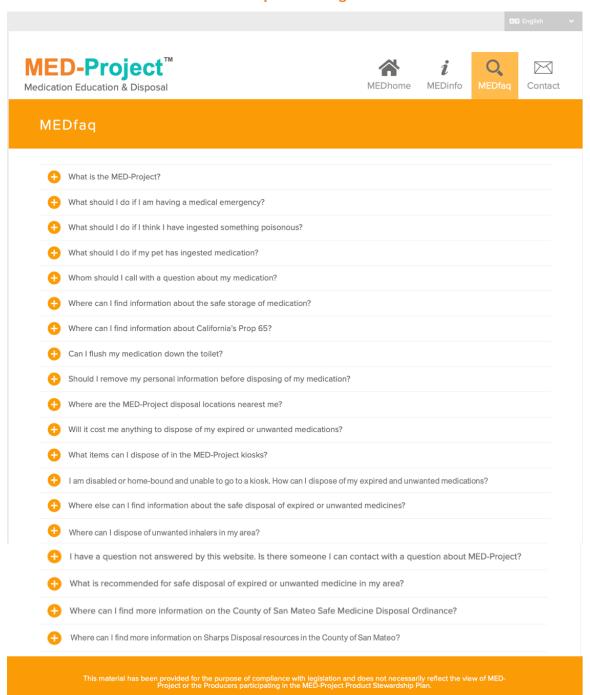
PLAY

Video Public Service Announcement (PSA):

PLAY

If you would like any of these materials emailed to you, contact sanmateocounty@med-project.org.

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MED-Project[™]
Medication Education & Disposal









CONTACT

If you are experiencing a medical emergency, please call 911. If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 1 (800)-222-1222. If you have questions about your medication, please call your health care provider.

For answers to some frequently asked questions about MED-Project, click here.

Residents

If you are a resident of San Mateo County and have questions about MED-Project, please contact:

1 (844) MED-PROJECT OR 1 (844) 633-7765 or (TTY: 711)

Pharmacies and Law Enforcement Offices

If you are a current kiosk drop-box host site, or a retail pharmacy, hospital/clinic pharmacy or law enforcement agency interested in hosting a drop-box, contact:

Dr. Victoria Travis, PharmD, MS, MBA National Program Director MED-Project LLC Phone: (844) 677-6532 Fax: (510) 686-8837

Email: sanmateocounty@med-project.org

Drug Producers

If you are drug producer interested in participating in the MED-Project stewardship plan contact:

Phone: (202) 495-3131

Email: compliance@med-project.org

This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the view of MED-Project or the Producers participating in the MED-Project Product Stewardship Plan.

Appendix QAppendix Q

Sample Media List

The following is a representative list of key media outlets to help educate Residents about proper disposal of expired or Unwanted Medicine. The list includes local print, online, television, and radio outlets, as well as outlets specifically targeting the diverse demographic communities within the County.

Print Outlets	Coverage Area	Website
Asian Journal (Filipino)	San Bruno	http://asianjournal.com
Bayspo (Japanese)	San Francisco	http://www.bayspo.com
Foster City Islander	Foster City	http://www.fostercityislander.com
Half Moon Bay Review	Half Moon Bay	http://www.hmbreview.com
Korean Times	San Francisco	http://sf.koreatimes.com
Marina Times	San Francisco	http://www.marinatimes.com
Pacifica Tribune	Pacifica	http://www.pacificatribune.com
San Francisco Bay View	San Francisco	http://sfbayview.com
San Francisco Business Times	San Francisco	http://www.bizjournals.com/sanfrancisco/news/
San Francisco Chronicle	San Francisco	http://www.sfgate.com
San Francisco Examiner	San Francisco	http://www.sfexaminer.com
San Mateo County Times	San Mateo	http://www.mercurynews.com/san-mateo-county-times
San Mateo Daily Journal	San Mateo	http://www.smdailyjournal.com
San Jose Mercury News	San Jose	http://www.mercurynews.com
Sing Tao Daily (Chinese)	San Francisco	https://www.singtaousa.com/?variant=zh-hk&fs=16
The Recorder	Silicon Valley	http://www.therecorder.com
World Journal (Chinese)	San Francisco	http://www.worldjournal.com

Television Outlets	Network
KDTV	Univision
KEMO	Azteca America
KGO	ABC
KNTV	NBC
KPIX	CBS
KQED	PBS
KRON	Media General
KSTS	Telemundo
KTVU	FOX

Radio Outlets	Coverage Area
KALW FM 91.7	San Francisco
KCBS AM 740	San Francisco
KCSF (College app radio)	San Francisco
KGO AM 810	San Francisco
KQED FM 88.5	San Francisco
KSFO AM 560	San Francisco
KUSF (College online radio)	San Francisco

Appendix R

Sample Digital and Local Social Networks

The following is a representative list of local organizations and their social media networks in the County.

Outlet	Facebook	Twitter
San Mateo County Sheriff's Office	/SMCSheriff	@SMCSheriff
San Mateo County Health System	/SMCHealth	@smchealth
Get Healthy San Mateo	/GetHealthySMC	@gethealthysmc
San Bruno Beacon	/San-Bruno-Beacon-128284043968223/	@SBBeacon
County of San Mateo	/sanmateoco	@sanmateoco
Half Moon Bay Review	/HMBreview	@hmbreview
Burlingame Police Department	/burlingamepolice/	@burlingamepd
City of Daly City	/dalycitygov/	@DalyCityGov
Daly City Police	/dalycitypolice	@DalyCityPD
Daly City Library	/DalyCityLibrary/	@dalycitylibrary
Daly City - Colma Chamber of Commerce	/dalycity.colmachamber	@dccchamber
Daly City Police Officers' Association	/DalyCityPOA	@DalyCityPOA
City of Brisbane	/brisbane94005	@brisbaneca
Brisbane Chamber of Commerce	/BrisbaneChamberofCommerce	@BrisbaneChamber
Brisbane Police Department	/BrisbanePD	N/A
Colma Police Dept.	/colmapolicedepartment	@ColmaPD
Town of Colma	/Colma-Recreation-Services- 1542638555973194	@TownofColma
South San Francisco	/CityofSouthSanFrancisco	@CityofSSF
South San Francisco Police Dept.	/SouthSanFranciscoPoliceDepartment	@SSFPolice

Outlet	Facebook	Twitter
South San Francisco Public Library	/ssfpubliclibrary	@SSFLibrary
South San Francisco Patch	/SouthSanFranciscoPatch	SSFPatch
City of San Bruno	/Sanbrunocommunityservicesdepartment	@CityofSanBruno
San Bruno Police Dept.	/San-Bruno-Police-Department- 233146236745593	@SanBrunoPolice
San Bruno Beacon	/San-Bruno-Beacon-128284043968223	@SBBeacon
City of Pacifica	/cityofpacifica	@Pacifica
Pacifica Police Dept.	/Pacifica-Police-Department- 718039501543161	@PacificaPolice
Pacifica Chamber of Commerce	/pacifica.chamber	@pacificacoc
Pacifica Tribune	/PacificaTribune	@PacificaTribune
Pacifica Patch	/PacificaPatch	@PacificaCAPatch
City of Millbrae	/City-of-Millbrae-637908862952645	N/A
Millbrae Police Dept.	/pages/Millbrae-Police- Department/112605438793771	N/A
Millbrae Chamber of Commerce	/MillbraeChamber	@MillbraeChamber
Millbrae Patch	/MillbraePatch	@MillbraePatch
City of Burlingame	/BurlingameCityHall	@BurlingameCity
Burlingame News	N/A	@burlingame_news
Burlingame Chamber of Commerce	/BurlingameChamber	@VisitBurlingame
Burlingame Police Dept.	/burlingamepolice	@BurlingamePD
Burlingame Patch	/BurlingameHillsboroughCAPatch	@BurlingamePatch
Hillsborough Police Dept.	/HillsboroughPD	@HillsboroughPD
City of San Mateo	/cityofsanmateo	@CityofSanMateo

Outlet	Facebook	Twitter
San Mateo Police Dept.	/CityofSanMateoPolice	@SanMateoPD
San Mateo Chamber of Commerce	/SanMateoChamber	@sanmateochamber
San Mateo County Health System	/SMCHealth	@SMCHealth
San Mateo Daily Journal	/smdailyjournal	@smdailyjournal
San Mateo News	N/A	@sanmateo_news
County of San Mateo	/CountyofSanMateo	@sanmateoco
San Mateo County Sheriff's Office	/SMCSheriff	@SMCSheriff
San Mateo City News	/SanMateoCountyNews	@sanmateoctynews
San Mateo Patch	/SanMateoPatch	@SanMateoPatch
City of Foster City	/CityofFosterCity	@CityofFC
Foster City Police	/FosterCityPolice	@FosterCityPD
Foster City News	N/A	@fostercitynews
Foster City Patch	/FosterCityPatch	@FosterCityPatch
City of Belmont Public Works Dept.	/CityofBelmontCA	@BelmontCA_PWORK
Belmont Police Dept.	/Belmont-Police- Department/165395370186926	@belmontcapolice
Belmont City Patch	/belmontcapatch	@BelmontCAPatch
City of San Carlos	/cityofsancarlos	@CityofSanCarlos
San Carlos Chamber of Commerce	N/A	@SanCarlosBiz
San Carlos Patch	/SanCarlosPatch	@SanCarlosPatch
San Carlos News	N/A	@sancarlos_news
Half Moon Bay Chamber of Commerce	/hmbchamber	@hmbchamber
Half Moon Bay Review	/HMBreview	@hmbreview

Outlet	Facebook	Twitter
Half Moon Bay Patch	/HalfMoonBayPatch	@HMoonBayPatch
City of Redwood City	/cityofredwoodcity	@RedwoodCity
Redwood City Police Dept.	/RedwoodCityPD	@RedwoodCityPD
Redwood City Patch	/RedwoodCityWoodsideCAPatch	@RedwoodCPatch
City of Menlo Park	/CityofMenIoPark	@CityofMenloPark
Menlo Park Police Dept.	/menloparkpd	@menloparkpd
Menlo Park Community Services	/menloparkcommunityservices	N/A
Menlo Park Patch	/MenloParkAthertonCAPatch/	@MenloParkPatch
Menlo Park Buzz	/Menlo-Park-Buzz-131027160272340	@menloparkbuzz
City of East Palo Alto	/CityOfEastPaloAlto	@eastpaloalto
East Palo Alto Police Dept.	/EastPaloAltoPD	@epapd
Town of Atherton	/TownOfAtherton	@townofatherton
Atherton Police Officers Association	/AthertonPOA	N/A
Town of Woodside	/pages/Town-of-Woodside	N/A
Portola Valley	N/A	N/A
NCPP San Mateo		@ncppsanmateo
Redwood City News		@redwoodcitynow
Stanford Healthcare	/stanfordhealthcare	@StanfordHealth
San Bruno Beacon	/San-Bruno-Beacon-128284043968223/ @SBBeacon	
San Mateo Patch	/SanMateoPatch	@sanmateopatch
San Mateo Times	/MercuryNews	@sanmateotimes

Appendix S

Communication Plan

	Government Agencies, Healthcare/Veterinary Organizations, Stakeholder Engagements					
Vehicle	Audience	Purpose / Message	Item / Event / Channel	Frequency / Date	Owner	
Email Distribution	Public health, healthcare, veterinary, law enforcement, and environmental organizations and trade associations	Promote why medicine return and how to use the program	Online, Email contact list on file	Once / Quarter: Send emails to provide program information (senior centers; community centers; vet clinics, healthcare clinics, etc.)	MED-Project	
Toolkit	Local government, retailers, other key stakeholders	Toolkit of materials for dissemination to network of support	Available on County website and by request	Active / Ongoing	MED-Project	
Stakeholder Engagement	Government agencies, local community groups, coalitions, organizations, associations	Promote program awareness, why medicine return and how to use the program	Newsletters, blogs, print material, URL on stakeholder websites, stakeholder toolkit	Active/Ongoing	Stakeholder	

	General Public						
Vehicle	Audience	Purpose / Message	Item / Event / Channel	Frequency / Date	Owner		
MED-Project Website	San Mateo County residents	Education about collection and safe disposal of meds, drop-off sites, events	MED-Project Website	Active / Ongoing	MED- Project		
MED-Project Call Line	San Mateo County residents	Call Center to answer questions from general public about drop-off locations and drug disposal	Call Center	Active / Ongoing	MED- Project		
Mail-back envelopes	San Mateo County residents – Disabled and Home-bound	Create awareness of disposal options in community	Call Center; MED- Project Website/Online, community newsletters, email, etc.	Once / Quarter: Send emails to provide program information (senior centers; community centers; vet clinics, healthcare clinics, etc.)	MED- Project		
MED-Project Social Media	San Mateo County	Create awareness of disposal options in community	Social Media marketing – Facebook, Twitter, etc.	Monthly: Post kiosk, MB and program information on social media (Facebook page and Twitter)	MED- Project		
PSA, Videos	San Mateo County residents	Create awareness and educate community on program	Available to stakeholders, County website, social media	Available for viewing on MED- Project website and Social Media accounts Use for social Media activity	MED- Project		
PSA, Radio	San Mateo County residents	Promote awareness of disposal program in community	Available to stakeholders, County website, social media	Available for listening on MED- Project website and Social Media accounts	MED- Project		

	General Public						
Vehicle	Audience	Purpose / Message	Item / Event / Channel	Frequency / Date	Owner		
Local Media Placements	San Mateo County residents - specific segments/groups of community	Promote why medicine return and how to use the program	Options outlined in Addendum 1: Broadcast Radio Pandora Internet Radio Zoned cable TV OTT Digital Media	Calendar to start after Plan approval: Media will be scheduled at least one activity every 3-4 months Minimum of 3 flights (as defined in addendum 1) will be completed during 12-month period after plan approval Activity will be a combination mix of the options outlined in Addendum 1	MED- Project		
COUNTY call Line	San Mateo County residents, collection locations and stakeholders	Answer questions about collection program.	COUNTY call line		County		
COUNTY website	San Mateo County residents	Promote Call Center and MED-Project Website.	COUNTY website		County		

	Collectors					
Vehicle	Audience	Purpose / Message	Item / Event / Channel	Frequency / Date	Owner	
Outreach to potential kiosk hosts	Potential Kiosk locations at Pharmacies, LEA & retail locations	Establishing Kiosk Drop-Off Sites distributed as throughout the County	Calls and emails	In progress / Ongoing	MED-Project	
Kiosk Toolkit	Pharmacies & Kiosk locations	Education about collection	Kiosk Instruction Kit with FAQs and How-To's for each kiosk location	In progress / Ongoing	MED-Project	
Kiosk Toolkit	Residents	Education on collection procedures	Signage, brochures, flyers to help guide residents to use kiosks, minimizing staff involvement	In progress / Ongoing	MED-Project	

