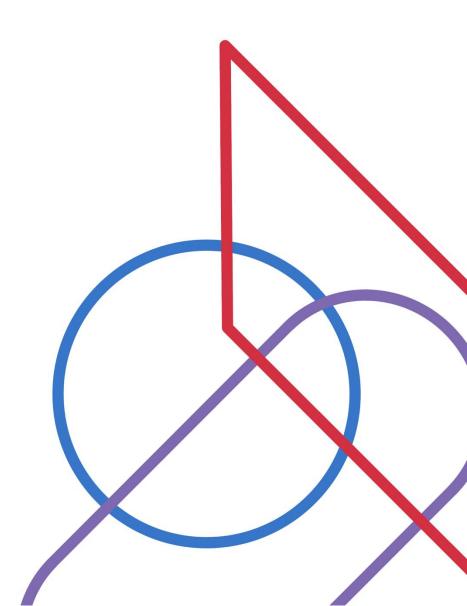


# A Product Stewardship Plan for Household Pharmaceutical Waste

### San Mateo County, CA

April 14, 2023; Revised September 18, 2023



## **Table of Contents**

I.	Introduction	6
	A. Participating Producers	7
П.	Contact Information	42
	Plan Definitions	
	Unwanted Medicine	
	Collection of Unwanted Medicine	
	A. Unwanted Medicine Collection Program Implementation	
	1. Outreach	
	2. Implementation	
	3. Convenience	
	4. Services	48
	B. Kiosk Drop-Off Sites	49
	1. Kiosk Drop-Off Site Locations	49
	2. Drop-Off Site Kiosk Placement and Maintenance Program	49
	3. Kiosk Specifications	50
	4. Kiosk Collection	51
	5. Collection Methods	52
	6. Kiosk Service	
	7. Unplanned Event Preparedness	
	C. Take-Back Events	
	1. Method	
	2. Procedures	
	3. Fees and Costs	
	D. Disposal of Unwanted Medicine	
	E. Mail-Back Services for Unwanted Medicine	
	1. Standard Mail-Back Services for Unwanted Medicine	
	2. Injector Mail-Back Services for Pre-filled Injector Products	
	3. Inhaler Mail-Back Services for Inhalers	
	4. Mail-Back Package Availability	
	5. Mail-Back Package Collection and Disposal	
VI.	Plan and Collection Goals	59
VII	Patient Privacy	60
VII	•••••	
	Training	
Х.	Vendor, Transporter, and Disposal Facility Information	
	A. Vendor	
	B. Reverse Distributor Facilities	
	C. Transporters and Carriers	
	D. Disposal Facilities	66
XI.	Unwanted Medicine Educational and Outreach Programming	67

Overview	-
A. Audiences	
B. Messages	
C. Tools/Communications Channels	
1. Phone	
2. MED-Project Website	68
3. Materials	69
4. Media Outreach	70
XII. Survey	71
XIII. Packaging	
XIV. Compliance with Applicable Laws, Regulations, and Other Legal	12
Requirements	72
A. DEA Controlled Substances Act and Implementing Regulations	
1. DEA Registration Modification	
B. United States Department of Transportation (DOT)	
C. California State Board of Pharmacy	76
XV. Annual Report	77
XVI. Coordination	
Appendix A	79
Participating Kiosk Drop-Off Sites	79
Mail-Back Distribution Location	
Appendix B	
Sample Kiosk and Signage	
Sample Kiosk Signage	
Sample Kiosk Signage	
Sample Kiosk Signage	85
Appendix C	86
April 16, 2019, Plan Approval	86
Appendix D	97
Sample Standard Mail-Back Package	
Sample Injector Mail-Back Package	
Sample Inhaler Mail-Back Package	89
Appendix E	90
Clean Harbors Aragonite, LLC Penalty Record	90
Curtis Bay Energy, LP Penalty Record	92
Heritage Thermal Service-Ohio Penalty Record	
Ross Incineration Services, Inc. Penalty Record	
Appendix F	
Sample Call Center Flow	
Appendix G	99

Sample MED-Project Website Pages	
Appendix H	
Single System of Promotion	

#### **Executive Summary**

MED-Project LLC ("MED-Project") develops, implements, and operates stewardship programs for Unwanted Medicine from households on behalf of hundreds of Producers (as defined in the County of San Mateo Safe Medicine Disposal Ordinance, San Mateo County Ordinance Code 4.116.010 – 4.116.190). MED-Project has substantial, practical, on-the-ground experience implementing Unwanted Medicine take-back programs in jurisdictions across the country, including the County of San Mateo. MED-Project currently administers an approved Stewardship Plan in the County of San Mateo County residents by collecting over 178,000 pounds of Unwanted Medicine from households since 2016 through a wide network of conveniently located unwanted medicine drop off sites. Further, MED-Project's outreach and education efforts have thus far resulted in over 43,000,000 impressions, stemming from its comprehensive education and outreach program.

#### I. Introduction

MED-Project, on behalf of the participating companies identified, 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 Producers to develop a Product Stewardship Program to finance and manage the collection, transportation, and disposal of Unwanted Medicine from San Mateo County Residents.

#### A. Participating Producers

MED-Project provides periodic updates, on a schedule established with the County of Producers that participate in the Plan in accordance with Ordinance 4.116.040(a). Below is a subset of the information provided on April 14, 2023. Certain identification information was removed for readability. The full list of MED-Project's participating Producers with all required contact and other information was provided as a separate attachment to the County on April 14, 2023.

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
3M Corporation	3M Corporation	3M Center 275- 5W-06	Saint Paul	Minnesota	55144	United States
3M Corporation	3M ESPE Dental Products	3M Center 275- 5W-06	Saint Paul	Minnesota	55144	United States
3M Corporation	3M Health Care	3M Center 275- 5W-06	Saint Paul	Minnesota	55144	United States
60 Degrees Pharmaceuticals, Inc.	60 Degrees Pharmaceuticals, Inc.	1025 Connecticut Ave NW Suite Suite 1000	Washington	District of Columbia	20036	United States
A-S Medication Solutions LLC	A-S Medication Solutions LLC	2401 Commerce Drive	Libertyville	Illinois	60048	United States
AbbVie Inc.	AbbVie Inc.	1 North Waukegan Road	North Chicago	Illinois	60064	United States
AbbVie Inc.	Allergan USA, Inc.	5 Giralda Farms	Madison	New Jersey	07940-1027	United States
AbbVie Inc.	Pharmacyclics, subsidiary of AbbVie Inc.	999 East Arques Avenue	Sunnyvale	California	94085	United States
ACADIA Pharmaceuticals Inc.	ACADIA Pharmaceuticals Inc.	12830 El Camino Real, Suite 400	San Diego	California	92130	United States
Accord Healthcare Inc.	Accord Healthcare Inc.	1009 Slater Road Suite 210-B	Durham	North Carolina	27703	United States
Accord Healthcare Inc.	Accord Biopharma	1009 Slater Road Suite 210-B	Durham	North Carolina	27703	United States
Acorda Therapeutics, Inc.	Acorda Therapeutics, Inc.	2 Blue Hill Plaza, 3rd Flr	Pearl River	New York	10965	United States
Advantice Health	Advantice Health	7 E Frederick Place Suite 100	Cedar Knolls	New Jersey	07927	United States
Advanz Pharma Group	Advanz Pharma Group	5 Canewood Industrial Park	Canewood	N/A	BB11005	Barbados
Afaxys Inc.	Afaxys Inc.	PO Box 20639	Charleston	South Carolina	29413	United States
Afaxys Inc.	Afaxys Pharmaceuticals (a division of Afaxys Inc.)	PO Box 20639	Charleston	South Carolina	29413	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Agile Therapeutics,	Agile Therapeutics,	500 College Road	Princeton	New Jersey	08540	United States
Inc.	Inc.	East, Suite 310				
Aidance Scientific,	Aidance Scientific,	184 Burnside	Woonsocket	Rhode Island	02895	United States
Inc.	Inc.	Avenue				
Ajanta Pharma USA	Ajanta Pharma USA	440 US Highway 22	Bridgewater	New Jersey	08807	United States
Inc.	Inc.	Ε.				
		STE 150				
Akebia Therapeutics,	Akebia Therapeutics,	245 First Street	Cambridge	Massachusetts	02142	United States
Inc.	Inc.					
Akebia Therapeutics,	Кегух	245 First Street	Cambridge	Massachusetts	02142	United States
Inc.	Biopharmaceuticals,					
	Inc.					
Alembic	Alembic	550 Hills Drive	Bedminster	New Jersey	07921	United States
Pharmaceuticals Inc.	Pharmaceuticals Inc.					
		Ste 104B				
Allegis	Allegis	276 Nissan	Canton	Mississippi	39046	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Parkway F100				
Almirall LLC	Almirall LLC	101 Lindenwood	Malvern	Pennsylvania	19355	United States
		Drive				
		Suite 400				
Alora	Alora	1880 McFarland	Alpharetta	Georgia	30005-1795	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Pkwy Ste 110				
Alora	Acella	1880 McFarland	Alpharetta	Georgia	30005-1795	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Parkway				
		Suite 110				
Alora	Avion	1880 McFarland	Alpharetta	Georgia	30005	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Parkway				
		Suite 105				
Alora	Sovereign	7590 Sand St	Ft. Worth	Texas	76118	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC					
Alora	Trigen Laboratories	1880 McFarland	Alpharetta	Georgia	30005-1795	United States
Pharmaceuticals, LLC	LLC	Pkwy Ste 110				

Parent Company	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Name						
Alora	Vertical	1880 McFarland	Alpharetta	Georgia	30005-1795	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Pkwy Ste 110				
Alvogen Pharma US,	Alvogen Pharma US,	44 Whippany Road	Morristown	New Jersey	07960	United States
Inc.	Inc.					
Alvogen Pharma US,	Almaject, Inc.	44 Whippany Road	Morristown	New Jersey	07960	United States
Inc.						
Alvogen Pharma US,	Almatica Pharma, LLC	44 Whippany Road	Morristown	New Jersey	07960	United States
Inc.						
Alvogen Pharma US,	Alvogen, Inc.	44 Whippany Road	Morristown	New Jersey	07960	United States
Inc.						
Alvogen Pharma US,	Norwich	6829 State Highway	Norwich	New York	13815	United States
Inc.	Pharmaceuticals, Inc.	12				
Amarin Pharma, Inc.	Amarin Pharma, Inc.	440 US Highway 22	Bridgewater	New Jersey	08807-2477	United States
,	,	Ste 300	0	,		
Amerisource Health	Amerisource Health	2550-A John Glenn	Columbus	Ohio	43217	United States
Services, LLC DBA:	Services, LLC DBA:	Avenue	Conditional		10217	office offices
American Health	American Health	/ Wellue				
Packaging	Packaging					
Amgen Inc.	Amgen Inc.	One Amgen Center	Thousand Oaks	California	91320	United States
Angen me.	Angen me.	Drive		California	51520	office states
Amgen Inc.	Amgen USA	One Amgen Center	Thousand Oaks	California	91320	United States
Angen ne.	Allgen 03A	Drive		Camornia	51520	Officed States
Amgen Inc.	Immunex Corporation	One Amgen Center	Thousand Oaks	California	91320	United States
Angen nic.	minutex corporation	Drive		California	91320	United States
Amgoning	Onyx Pharmaceuticals	249 N. Grand	South San Francisco	California	94080	United States
Amgen Inc.	Unix Pharmaceuticais	Avenue	South San Francisco	California	94080	United States
America	Amneal		Dridaowator	New Jersey	00007	
Amneal		400 Crossing Blvd	Bridgewater	New Jersey	08807	United States
Pharmaceuticals LLC	Pharmaceuticals LLC	Third Floor			04720	
Amphastar	Amphastar	11570 Sixth Street	Rancho Cucamonga	California	91730	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.					
Amphastar	International	1886 Santa Anita	South El Monte	California	91733	United States
Pharmaceuticals, Inc.	Medication Systems,	Ave				
	LTD					

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Amring Pharmaceuticals Inc.	Amring Pharmaceuticals Inc.	1205 Westlakes Drive Suite 275	Berwyn	Pennsylvania	19312	United States
Amryt Pharmaceuticals, Inc.	Amryt Pharmaceuticals, Inc.	160 federal St., 21st FL	Boston	Massachusetts	02110	United States
ANI Pharmaceuticals, Inc.	ANI Pharmaceuticals, Inc.	210 West Main Street	Baudette	Minnesota	56623	United States
Apotex Holdings, Inc.	Apotex Holdings, Inc.	150 Signet Drive	Toronto	Ontario	M9L 1T9	Canada
Apotex Holdings, Inc.	Apotex Corp.	2400 N. Commerce Parkway Suite 400	Weston	Florida	33326	United States
Apotex Holdings, Inc.	Aveva Drug Delivery Systems, Inc.	2400 N. Commerce Parkway Suite 400	Weston	Florida	33326	United States
Aprecia Pharmaceuticals, LLC	Aprecia Pharmaceuticals, LLC	10901 Kenwood Road	Blue Ash	Ohio	45242	United States
Arbor Pharmaceuticals, LLC	Arbor Pharmaceuticals, LLC	6 Concourse Parkway Suite 1800	Atlanta	Georgia	30328	United States
Arbor Pharmaceuticals, LLC	Wilshire Pharmaceuticals	6 Concourse Parkway Suite 1800	Atlanta	Georgia	30328	United States
Arcadia Consumer Healthcare	Arcadia Consumer Healthcare	440 US Highway 22 - Suite 210	Bridegwater	New Jersey	08807	United States
Arcadia Consumer Healthcare	Kramer Laboratories Inc	440 US Highway 22	Bridgewater	New Jersey	08807	United States
Arcadia Consumer Healthcare	Rowpar Pharmaceuticals	440 US Highway 22 - Suite 210	Bridegwater	New Jersey	08807	United States
Arcutis Biotherapeutics, Inc	Arcutis Biotherapeutics, Inc	3027 Townsgate Road, Suite 300	Westlake Village	California	91361	United States
Ardelyx	Ardelyx	400 Fifth Avenue Suite 210	Waltham	Massachusetts	02451	United States
Armas Pharmaceuticals LLC	Armas Pharmaceuticals LLC	303 West Main Street	Freehold	New Jersey	07728	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Suite 300				
Ascend Therapeutics US, LLC	Ascend Therapeutics US, LLC	15 Mount Kemble Avenue	Morristown	New Jersey	07960	United States
Ascendis Pharma A/S	Ascendis Pharma A/S	Tuborg Boulevard 12	Hellerup	N/A	2900	Denmark
Ascendis Pharma A/S	Ascendis Pharma Endocrinology, Inc.	902 Carnegie Center Blvd., Ste 300	Princeton	New Jersey	08540	United States
Ascendis Pharma A/S	Ascendis Pharma, Inc.	1000 Page Mill Road	Palo Alto	California	94304	United States
Astellas Pharma US, Inc.	Astellas Pharma US, Inc.	1 Astellas Way	Northbrook	Illinois	60062	United States
AstraZeneca Pharmaceuticals LP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike PO Box 15437	Wilmington	Delaware	19850-5437	United States
Aurobindo Pharma, Ltd.	Aurobindo Pharma, Ltd.	279 Princeton Hightstown Road	East Windsor	New Jersey	08520-1401	United States
Aurobindo Pharma, Ltd.	Acrotech BioPharma Inc.	279 Princeton- Hightstown Road	East Windsor	New Jersey	08520	United States
Aurobindo Pharma, Ltd.	Aurobindo Pharma USA, Inc.	279 Princeton Hightstown Road	East Windsor	New Jersey	08520-1401	United States
Aurobindo Pharma, Ltd.	AuroHealth, LLC	279 Princeton Hightstown Road	East Windsor	New Jersey	08520	United States
Aurobindo Pharma, Ltd.	Vespyr Brands Inc.	279 Princeton Hightstown Road	East Windsor	New Jersey	08520-1401	United States
Axsome Therapeutics, Inc.	Axsome Therapeutics, Inc.	22 Cortlandt Street 16th Floor	New York	New York	10007	United States
Azurity Pharmaceuticals, Inc.	Azurity Pharmaceuticals, Inc.	841 Woburn Street	Wilmington	Massachusetts	01887-3414	United States
B.F. Ascher & Co., Inc.	B.F. Ascher & Co., Inc.	15501 W. 109th St.	Lenexa	Kansas	66219	United States
Bantry Pharma, LLC	Bantry Pharma, LLC	5400 Laurel Springs Parkway, Suite 803 G	Suwanee	Georgia	30024	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Bausch + Lomb	Bausch + Lomb	400 Somerset Corporate Blvd.	Bridgewater	New Jersey	08807	United States
Bausch Health Companies	Bausch Health Companies	1400 Goodman Street North	Rochester	New York	14609	United States
Bausch Health Companies	Salix	400 Somerset Corporate Blvd	Bridgewater	New Jersey	08807	United States
Baxter Healthcare Corporation	Baxter Healthcare Corporation	One Baxter Parkway	Deerfield	Illinois	60015	United States
Bayer HealthCare LLC	Bayer HealthCare LLC	100 Bayer Boulevard	Whippany	New Jersey	07981-0915	United States
Bayer HealthCare LLC	Bayer Consumer Care Holdings LLC	100 Bayer Blvd	Whippany	New Jersey	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals Inc.	100 Bayer Blvd	Whippany	New Jersey	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals LLC	800 Dwight Way	Berkeley	California	94710	United States
BestCo, Inc.	BestCo, Inc.	288 Mazeppa Road	Mooresville	North Carolina	28027	United States
Beutlich Pharmaceuticals LLC	Beutlich Pharmaceuticals LLC	7775 S. US HWY 1, Unit H	Bunnell	Florida	32110	United States
Biocon Pharma, Inc.	Biocon Pharma, Inc.	485 Highway 1 South, Suite B305	Iselin	New Jersey	08830	United States
Biogen Inc.	Biogen Inc.	225 Binney Street	Cambridge	Massachusetts	02142	United States
Biological E Limited	Biological E Limited	Road No. 35, Jubilee Hills	Hyderabad, Telangana	N/A	500033	India
Biological E Limited	BE Pharmaceuticals, Inc.	203 New Edition Ct.	Cary	North Carolina	27511	United States
BioMarin Pharmaceutical Inc.	BioMarin Pharmaceutical Inc.	105 Digital Drive	Novato	California	94949	United States
Bionpharma Inc.	Bionpharma Inc.	600 Alexander Road Suite 2-4B	Princeton	New Jersey	08540	United States
Blistex Inc.	Blistex Inc.	1800 Swift Drive	Oak Brook	Illinois	60523	United States
Blueprint Medicines Corporation	Blueprint Medicines Corporation	45 Sidney St	Cambridge	Massachusetts	02139	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim USA, Inc.	900 Ridgebury Road	Ridgefield	Connecticut	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Animal Health Division	3239 Satellite Blvd	Duluth	Georgia	30096-4640	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Animal Health Puerto Rico LLC	P.O. Box 601	Barceloneta	Puerto Rico	00617	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road	Ridgefield	Connecticut	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Vetmedica, Inc.	2612 Belt Highway	St. Joseph	Missouri	64506	United States
Bridges	Bridges	27070 Miles Road, Suite A	Solon	Ohio	44139	United States
Bridges	Clarion Brands LLC	27070 Miles Road, Suite A	Solon	Ohio	44139	United States
Bristol Myers Squibb Company	Bristol Myers Squibb Company	P.O. Box 4500	Princeton	New Jersey	08543-4500	United States
Bristol Myers Squibb Company	Bristol Myers Squibb Pharma Company	P.O. Box 4500	Princeton	New Jersey	08543-4500	United States
Bristol Myers Squibb Company	Celgene Corporation	86 Morris Avenue	Summit	New Jersey	07901	United States
Bristol Myers Squibb Company	E.R. Squibb & Sons, LLC	P.O. Box 4500	Princeton	New Jersey	08543-4500	United States
Bristol Myers Squibb Company	MyoKardia, Inc	1000 Sierra Point Pkwy	Brisbane	California	94005	United States
Cameron Pharmaceuticals, LLC	Cameron Pharmaceuticals, LLC	12305 Westport Rd., Suite 205	Louisville	Kentucky	40245	United States
Catalent Pharma Solutions, Inc.	Catalent Pharma Solutions, Inc.	14 Schoolhouse Road	Somerset	New Jersey	08873	United States
Catalent Pharma Solutions, Inc.	Catalent Anagni S.r.l.	STRADA PROVINCIALE 12 CASILINA 41, ANAGNI (FONTANA DEL CERASO)	Frosinone	N/A	03012	Italy

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Catalent Pharma Solutions, Inc.	Catalent Argentina S.A.I.C.	Avenida Bernabe Marquez 691, Villa Loma Hermosa	Buenos Aires	N/A	1657	Argentina
Catalent Pharma Solutions, Inc.	Catalent Belgium S.A.	Font Saint Landry 10	Brussels	N/A	1120	Belgium
Catalent Pharma Solutions, Inc.	Catalent CTS (Edinburgh) Limited	1 Inchwood Park	Bathgate	N/A	EH48 2FY	United Kingdom
Catalent Pharma Solutions, Inc.	Catalent CTS, LLC	10245 Hickman Mills Dr	Kansas City	Missouri	64137	United States
Catalent Pharma Solutions, Inc.	Catalent France Beinheim S.A.	74 Rue Principale	Beinheim	N/A	67930	France
Catalent Pharma Solutions, Inc.	Catalent Germany Eberbach GmbH	Gammelsbacher Strasse 2	Eberbach, Baden	N/A	69412	Germany
Catalent Pharma Solutions, Inc.	Catalent Germany Schorndorf GmbH	Steinbeisstrasse 2	Schorndorf	N/A	D-73614	Germany
Catalent Pharma Solutions, Inc.	Catalent Greenville, Inc.	1240 Sugg Parkway	Greenville	North Carolina	27834	United States
Catalent Pharma Solutions, Inc.	Catalent Indiana, LLC	1300 S Patterson Drive	Bloomington	Indiana	47403	United States
Catalent Pharma Solutions, Inc.	Catalent Massachusetts, LLC	190 Everett Avenue	Chelsea	Massachusetts	02150	United States
Catalent Pharma Solutions, Inc.	Catalent Micron Technologies Limited	Crossways Boulevard, Crossways	Dartford, Kent	N/A	DA2 6QY	United Kingdom
Catalent Pharma Solutions, Inc.	Catalent Micron Technologies, Inc.	333 Phoenixville Pike	Malvern	Pennsylvania	19355	United States
Catalent Pharma Solutions, Inc.	Catalent Nottingham Limited	8 Orchard Place, Nottingham Business Park	Nottingham, Nottinghamshire	N/A	NG8 6PX	United Kingdom
Catalent Pharma Solutions, Inc.	Catalent Ontario Limited	2125 Ambassador Drive	Windsor	Ontario	N9C 3R5	Canada
Catalent Pharma Solutions, Inc.	Catalent Pharma Solutions Limited	Frankland Road, Blagrove	Swindon, Wiltshire	N/A	SN5 8RU	United Kingdom
Catalent Pharma Solutions, Inc.	Catalent Pharma Solutions, LLC	14 Schoolhouse Road	Somerset	New Jersey	08873	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Catalent Pharma	Catalent U.K. Swindon	Frankland Road,	Swindon, Wiltshire	N/A	SN5 8RU	United Kingdom
Solutions, Inc.	Zydis Limited	Blagrove	,	,		U
Chartwell RX, LLC	Chartwell RX, LLC	77 Brenner Drive	Congers	New York	10920	United States
Chiesi USA, Inc.	Chiesi USA, Inc.	175 Regency	Cary	North Carolina	27518	United States
(formerly	(formerly	Woods				
Cornerstone	Cornerstone	Suite 600				
Therapeutics, Inc.)	Therapeutics, Inc.)					
Church & Dwight	Church & Dwight	469 N Harrison St	Princeton	New Jersey	08540-3597	United States
Company, Inc.	Company, Inc.					
Cintex Services, LLC	Cintex Services, LLC	5400 Laurel Springs Parkway, Suite 803A	Suwanee	Georgia	30024	United States
CitraGen	CitraGen	3789 Spinnaker	Fremont	California	94538	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.	Court				
Clovis Oncology, Inc.	Clovis Oncology, Inc.	5500 Flatiron	Boulder	Colorado	80301	United States
		Parkway				
CMP Pharma, Inc	CMP Pharma, Inc	PO Box 147 8026 East Marlboro	Farmville	North Carolina	27828	United States
		Rd.				
Colgate Oral Pharmaceuticals, Inc.	Colgate Oral Pharmaceuticals, Inc.	300 Park Avenue	New York	New York	10022	United States
Collegium	Collegium	100 Technology	Stoughton	Massachusetts	02072	United States
Pharmaceutical, Inc.	Pharmaceutical, Inc.	Center Drive, Suite 300				
Collegium	BioDelivery Sciences,	4131 ParkLake	Raleigh	North Carolina	27612	United States
Pharmaceutical, Inc.	Inc.	Avenue, Suite 225	-			
Corcept Therapeutics	Corcept Therapeutics	149 Commonwealth Drive	Menlo Park	California	94025	United States
Corium, Inc.	Corium, Inc.	4558 50th Street SE	Grand Rapids	Michigan	49512	United States
Cosette	Cosette	111 Coolidge St.	South Plainfield	New Jersey	07080	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.			,		
Covis Pharma GmbH	Covis Pharma GmbH	Baarn, Zug Branch Grafenauweg 12	Zug	N/A	СН- 6300	Switzerland

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Covis Pharma GmbH	AMAG Pharma USA, Inc.	Baarn, Zug Branch Grafenauweg 12	Zug	N/A	CH- 6300	Switzerland
Covis Pharma GmbH	AMAG Pharmaceuticals, Inc.	Baarn, Zug Branch Grafenauweg 12	Zug	N/A	CH- 6300	Switzerland
Covis Pharma GmbH	Covis Pharma US, Inc.	1150 1st Ave. Suite 940	King of Prussia	Pennsylvania	19406	United States
Creekwood Pharmaceuticals LLC	Creekwood Pharmaceuticals LLC	1130, U.S. 46 W, Suite 21	Parsippany	New Jersey	07054	United States
Crown Laboratories, Inc.	Crown Laboratories, Inc.	349 Lafe Cox Drive	Johnson City	Tennessee	37604	United States
CSL Behring, LLC	CSL Behring, LLC	500 N. Gulph Rd	King of Prussia	Pennsylvania	19406	United States
CTI BioPharma Corp.	CTI BioPharma Corp.	3101 Western Avenue, Suite #800	Seattle	Washington	98121	United States
Currax Pharmaceuticals LLC dba Cypress, Macoven, Hawthornn	Currax Pharmaceuticals LLC dba Cypress, Macoven, Hawthornn	155 FRANKLIN ROAD, SUITE 450	BRENTWOOD	Tennessee	37027	United States
Daiichi Sankyo, Inc.	Daiichi Sankyo, Inc.	211 Mt. Airy Rd.	Basking Ridge	New Jersey	07920	United States
Daiichi Sankyo, Inc.	American Regent, Inc.	One Luitpold Drive	Shirley	New York	11967	United States
Daiichi Sankyo, Inc.	HBT Labs Inc.	536 Vanguard Way	Brea	California	92821	United States
DAVION INC.	DAVION INC.	2 PROGRESS ROAD	NORTH BRUNSWICK	New Jersey	08902	United States
Dechra Veterinary Products North America	Dechra Veterinary Products North America	7015 College Blvd Ste 525	Leawood	Kansas	66211-1551	United States
Deciphera Pharmaceuticals, LLC	Deciphera Pharmaceuticals, LLC	200 Smith Street Building B 3rd Floor	Waltham	Massachusetts	02451	United States
Derma Care Research Labs, LLC	Derma Care Research Labs, LLC	440 Fentress Blvd	Daytona Beach	Florida	32114	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
DermaRite Industries	DermaRite Industries	7777 Westside Avenue	North Bergen	New Jersey	07047	United States
Dermazone Solutions, Inc.	Dermazone Solutions, Inc.	2440 30th Avenue North Dermazone Solutions	St. Petersburg	Florida	33713	United States
DLC Laboratories, Inc.	DLC Laboratories, Inc.	7008 Marcelle Street	Paramount	California	90723	United States
DSE Healthcare Solutions, LLC	DSE Healthcare Solutions, LLC	105 Fieldcrest Avenue Suite 502A	Edison	New Jersey	08837	United States
DSE Healthcare Solutions, LLC	Numark Brands, Inc.	105 Fieldcrest Avenue Suite 502A	Edison	New Jersey	08837	United States
Duchesnay USA, Inc.	Duchesnay USA, Inc.	919 Conestoga Road, Building I Suite 203	Rosemont	Pennsylvania	19010	United States
Duchesnay USA, Inc.	Analog Pharma, Inc.	919 Conestoga Road, Building I Suite 201	Rosemont	Pennsylvania	19010	United States
Duchesnay USA, Inc.	Medunik USA, Inc.	919 Conestoga Road, Building I Suite 202	Rosemont	Pennsylvania	19010	United States
Dukal LLC	Dukal LLC	2 Fleetwood Court	Ronkonkoma	New York	11779	United States
e5 Pharma, LLC	e5 Pharma, LLC	225 Mizner Boulevard Ste 770	Boca Raton	Florida	33432	United States
e5 Pharma, LLC	Mizner Bioscience, LLC	225 ME Mizner Boulevard Suite 760	Boca Raton	Florida	33432	United States
Eckson Labs, LLC	Eckson Labs, LLC	5400 Laurel Springs Parkway, Suite 803B	Suwanee	Georgia	30024	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Edenbridge Pharmaceuticals, LLC	Edenbridge Pharmaceuticals, LLC	169 Lackawanna Avenue Suite 110	Parsippany	New Jersey	07054	United States
Eisai, Inc.	Eisai, Inc.	100 Tice Blvd	Wood Cliff Lake	New Jersey	07677	United States
Elanco US Inc.	Elanco US Inc.	2500 Innovation Way N	Greenfield	Indiana	46140-9163	United States
Eli Lilly and Company	Eli Lilly and Company	Lilly Corporate Center	Indianapolis	Indiana	46285	United States
Elite Laboratories, Inc	Elite Laboratories, Inc	165 Ludlow Avenue	Northvale	New Jersey	07647	United States
EMD Serono, Inc.	EMD Serono, Inc.	One Technology Place	Rockland	Massachusetts	02370	United States
Emergent Devices Inc (formerly known as Adapt Pharma Inc)	Emergent Devices Inc (formerly known as Adapt Pharma Inc)	401 Plymouth Rd Ste 400	Plymouth Meeting	Pennsylvania	19462-1645	United States
Emmaus Medical, Inc.	Emmaus Medical, Inc.	21250 Hawthorne Blvd., Suite 800	Torrance	California	90503	United States
Encube Ethicals, Inc.	Encube Ethicals, Inc.	200 Meredith Drive, Suite 101A	Durham	North Carolina	27713	United States
Endo Pharmaceuticals Inc.	Endo Pharmaceuticals Inc.	1400 Atwater Drive	Malvern	Pennsylvania	19355	United States
Endo Pharmaceuticals Inc.	Par Pharmaceutical Companies, Inc.	6 Ram Ridge Rd	Chestnut Ridge	New York	10977	United States
Endo Pharmaceuticals Inc.	Par Pharmaceutical, Inc.	6 Ram Ridge Road	Chestnut Ridge	New York	10977	United States
Endo Pharmaceuticals Inc.	Par Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	6 Ram Ridge Rd	Chestnut Ridge	New York	10977	United States
Endo Pharmaceuticals Inc.	Par Sterile Products, LLC (d/b/a Par Pharmaceutical)	6 Ram Ridge Road	Chestnut Ridge	New York	10977	United States
EPI Health, LLC	EPI Health, LLC	174 Meeting Street, Suite 200	Charleston	South Carolina	29401	United States
Epizyme, Inc.	Epizyme, Inc.	400 Technology Sq. 4th Floor	Cambridge	Massachusetts	02139	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Esperion	Esperion	3891 Ranchero Drive	Ann Arbor	Michigan	48108	United States
		Suite 150				
Eton Pharmaceuticals, Inc.	Eton Pharmaceuticals, Inc.	21925 W Field Parkway, Suite 235	Deer Park	Illinois	60010	United States
Exelixis, Inc.	Exelixis, Inc.	1851 Harbor Bay Parkway	Alameda	California	94502	United States
Eywa Pharma Inc.	Eywa Pharma Inc.	2 Research Way, Floor #3	Princeton	New Jersey	08540	United States
Ferring Pharmaceuticals Inc.	Ferring Pharmaceuticals Inc.	100 Interpace Parkway	Parsippany	New Jersey	07054	United States
Forte Bio-Pharma LLC	Forte Bio-Pharma LLC	8311 W. Sunset Rd. #150	Las Vegas	Nevada	89113	United States
Forte Bio-Pharma LLC	FH2 Pharma LLC	9205 W. Russell Rd Ste 240	Las Vegas	Nevada	89148	United States
Forte Bio-Pharma LLC	Intra-Sana Laboratories	7455 Arroyo Crossing Ste 220	Las Vegas	Nevada	89113	United States
Foundation Consumer Healthcare, LLC	Foundation Consumer Healthcare, LLC	106 Isabella Street Suite 602	Pittsburgh	Pennsylvania	15212	United States
Foundation Consumer Healthcare, LLC	Foundation Consumer Brands, LLC	106 Isabella Street Suite 602	Pittsburgh	Pennsylvania	15212	United States
Fourstar Group USA, Inc.	Fourstar Group USA, Inc.	189 Main Street Suite 31	Milford	Massachusetts	01757	United States
Fresenius Kabi USA, LLC	Fresenius Kabi USA, LLC	Three Corporate Drive	Lake Zurich	Illinois	60047	United States
Galderma Laboratories, L.P.	Galderma Laboratories, L.P.	14501 North Freeway	Fort Worth	Texas	76177	United States
Garcoa Laboratories, Inc.	Garcoa Laboratories, Inc.	26135 Mureau Road	Calabasas	California	91302	United States
GenBioPro, Inc.	GenBioPro, Inc.	3651 Lindell Rd., P.O. Box 32011	Las Vegas	Nevada	89103	United States

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Genus Lifesciences Inc.	Genus Lifesciences Inc.	514 North 12th Street	Allentown	Pennsylvania	18102	United States
Gilead Sciences, Inc.	Gilead Sciences, Inc.	333 Lakeside Drive	Foster City	California	94404	United States
Gilead Sciences, Inc.	Asegua Therapeutics LLC	333 Lakeside Drive	Foster City	California	94404	United States
Gilead Sciences, Inc.	Gilead Sciences, LLC	333 Lakeside Drive	Foster City	California	94404	United States
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC	GlaxoSmithKline Consumer Healthcare Holdings (US) LLC	184 Liberty Corner Road	Warren	New Jersey	07059	United States
GlaxoSmithKline, LLC	GlaxoSmithKline, LLC	2929 Walnut Street, Suite 1700	Philadelphia	Pennsylvania	19104	United States
GlaxoSmithKline, LLC	ViiV Healthcare Company	5 Moore Drive	RTP	North Carolina	27709	United States
Glenmark Pharmaceuticals Inc., USA	Glenmark Pharmaceuticals Inc., USA	750 Corporate Drive	Mahwah	New Jersey	07430	United States
Granard Pharmaceuticals	Granard Pharmaceuticals	1967 Highway 34	Wall	New Jersey	07719	United States
Granard Pharmaceuticals	Royal Pharmaceuticals	1967 Highway 34	Wall	New Jersey	07719	United States
Granard Pharmaceuticals	Seton Pharmaceuticals, LLC	1967 Highway 34 Suite 103	Wall	New Jersey	07719	United States
Gregory Pharmaceutical Holdings	Gregory Pharmaceutical Holdings	501 Fifth Street	Bristol	Tennessee	37620	United States
Grifols Shared Services North America Inc.	Grifols Shared Services North America Inc.	2410 Grifols Way	Los Angeles	California	90032	United States
Grifols Shared Services North America Inc.	Grifols Biologicals LLC	5555 Valley Blvd.	Los Angeles	California	90032	United States
Grifols Shared Services North America Inc.	Grifols Therapeutics LLC	8368 US 70 Business Hwy West	Clayton	North Carolina	27520	United States

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Grifols Shared Services North America Inc.	Instituto Grifols S.A.	Poligono Industrial Levante C Can Guasc, 2	Parets Del Valles	N/A	08150	Spain
Grifols Shared Services North America Inc.	Laboratorios Grifols S.A.	Calle Logistica 2 Poligono Industrial Z	Parets del Valles	N/A	08150	Spain
Guardian Drug Company	Guardian Drug Company	2 Charles Court	Dayton	New Jersey	08810	United States
Harmony Biosciences, LLC	Harmony Biosciences, LLC	630 W. Germantown Pike, Suite 215	Plymouth Meeting	Pennsylvania	19462	United States
Helsinn Therapeutics (US), Inc	Helsinn Therapeutics (US), Inc	170 Wood Ave South	Iselin	New Jersey	08830	United States
Henry Schein, Inc	Henry Schein, Inc	135 Duryea Rd, E- 355	MELVILLE	New York	11747	United States
HLS Therapeutics (USA), Inc.	HLS Therapeutics (USA), Inc.	919 Conestoga Road, Building Three Suite 310	Rosemont	Pennsylvania	19010	United States
Horizon Therapeutics plc.	Horizon Therapeutics plc.	1 Horizon Way	Deerfield	Illinois	60015	United States
Horizon Therapeutics plc.	Horizon Medicines LLC	1 Horizon Way	Deerfield	Illinois	60015	United States
Horizon Therapeutics plc.	Horizon Therapeutics USA, Inc.	1 Horizon Way	Deerfield	Illinois	60015	United States
i-Health, Inc.	i-Health, Inc.	55 Sebethe Dr.	Cromwell	Connecticut	06416	United States
Idorsia Pharmaceuticals US Inc.	Idorsia Pharmaceuticals US Inc.	One Radnor Corporate Center, Suite 101 100 Matsonford Rd.	Radnor	Pennsylvania	19087	United States
Incyte Corporation	Incyte Corporation	1801 Augustine Cut-Off	Wilmington	Delaware	19803	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Indivior Inc	Indivior Inc	10710 Midlothian Turnpike Suite 125	Richmond	Virginia	23235	United States
Infirst Healthcare Inc	Infirst Healthcare Inc	8 Church Lane	Westport	Connecticut	06880	United States
Ingenus Pharmaceuticals, LLC	Ingenus Pharmaceuticals, LLC	4901 Vineland Road	Orlando	Florida	32811	United States
Insmed Incorporated	Insmed Incorporated	Suite 260 700 US Highway 202 / 206	Bridgewater	New Jersey	08807	United States
Invagen Pharmaceuticals, Inc.	Invagen Pharmaceuticals, Inc.	7 Oser Avenue	Hauppauge	New York	11788	United States
Invagen Pharmaceuticals, Inc.	Cipla Therapeutics, Inc.	10 Independence Blvd. Suite 400	Warren	New Jersey	07059	United States
Invagen Pharmaceuticals, Inc.	Cipla USA, Inc.	10 Independence Blvd., Suite 300	Warren	New Jersey	07059	United States
Invagen Pharmaceuticals, Inc.	Exelan Pharmaceuticals, Inc.	370 Camino Gardens Blvd. Suite 204	Boca Raton	Florida	30046	United States
Ipsen Biopharmaceuticals, Inc	Ipsen Biopharmaceuticals, Inc	One Main St 7th Floor	Cambridge	Massachusetts	02142	United States
J.R. Watkins LLC	J.R. Watkins LLC	1111 Broadway	Oakland	California	94607	United States
James Alexander Corporation	James Alexander Corporation	845 Route 94	Frelinghuysen	New Jersey	07825	United States
Jazz Pharmaceuticals, Inc.	Jazz Pharmaceuticals, Inc.	3170 Porter Drive	Palo Alto	California	94304	United States
Johnson & Johnson	Johnson & Johnson	One Johnson & Johnson Plaza WH-7113	New Brunswick	New Jersey	08933	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Johnson & Johnson	Actelion	5000 Shoreline Ct	South San Francisco	California	94080	United States
		STE 200				
Johnson & Johnson	CoTherix	1125 Trenton- Harbourton Road,	Titusville	New Jersey	08560	United States
Johnson & Johnson	Ethicon, Inc.	One Johnson & Johnson Plaza WH-7113	New Brunswick	New Jersey	08933	United States
Johnson & Johnson	Janssen Biotech, Inc.	800/850 Ridgeview Drive	Horsham	Pennsylvania	19044	United States
Johnson & Johnson	Janssen Pharmaceuticals, Inc.	1125 Trenton- Harbourton Road	Titusville	New Jersey	08560	United States
Johnson & Johnson	Janssen Products, LP	1000 US-2020	Raritan	New Jersey	08869	United States
Johnson & Johnson	Johnson & Johnson Surgical Vision Inc	1700 E Saint Andrew Pl	Santa Ana	California	92705	United States
Johnson & Johnson	Patriot Pharmaceuticals, LLC	200 Tournament Drive	Horsham	Pennsylvania	19044	United States
Johnson & Johnson Consumer, Inc.	Johnson & Johnson Consumer, Inc.	199 Grandview Road	Skillman	New Jersey	08558	United States
Kaleo Inc.	Kaleo Inc.	111 Virginia Street Suite 300	Richmond	Virginia	23219	United States
Karyopharm Therapeutics, Inc.	Karyopharm Therapeutics, Inc.	85 Wells Avenue, Suite 210	Newton	Massachusetts	02459	United States
KMM Pharmaceuticals, LLC	KMM Pharmaceuticals, LLC	5400 Laurel Springs parkway, Suite 803C	Suwanee	Georgia	30024	United States
Kobayashi Healthcare International, Inc.	Kobayashi Healthcare International, Inc.	245 Kraft Drive	Dalton	Georgia	30721	United States
Kobayashi Healthcare International, Inc.	Alva-Amco Pharmacal Companies, Inc.	7711 N Merrimac Avenue	Niles	Illinois	60714-3423	United States
Kowa Pharmaceuticals America, Inc.	Kowa Pharmaceuticals America, Inc.	530 Industrial Park Blvd.	Montgomery	Alabama	36117	United States

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Kt Health, LLC	Kt Health, LLC	584 East 1100 South 4	American Fork	Utah	84003	United States
Kyowa Kirin, Inc.	Kyowa Kirin, Inc.	135 Route 202-206 Suite 6	Bedminster	New Jersey	07921	United States
Laurus Generics Inc.	Laurus Generics Inc.	400 Connell Drive, Suite 5200	Berkeley Heights	New Jersey	07922	United States
Leadiant Biosciences, Inc.	Leadiant Biosciences, Inc.	9841 Washingtonian Blvd. Suite 500	Gaithersburg	Maryland	20878	United States
LEO Pharma A/S	LEO Pharma A/S	7 Giralda Farms 2nd Floor	Madison	New Jersey	07940	United States
LEO Pharma A/S	LEO Pharma Inc.	7 Giralda Farms 2nd Floor	Madison	New Jersey	07940	United States
LIFESTAR PHARMA LLC	LIFESTAR PHARMA LLC	1200 MACARTHUR BOULEVARD	MAHWAH	New Jersey	07430	United States
Lundbeck Pharmaceuticals LLC	Lundbeck Pharmaceuticals LLC	Six Parkway N Ste 400	Deerfield	Illinois	60015	United States
Lupin Pharmaceuticals, Inc. (LPI)	Lupin Pharmaceuticals, Inc. (LPI)	111 S. Calvert St.	Baltimore	Maryland	21202	United States
Mallinckrodt PLC	Mallinckrodt PLC	College Business & Technology Park Cruiserath	Blanchardstown	Dublin	15	Ireland
Mallinckrodt PLC	Mallinckrodt ARD LLC	675 McDonnell Blvd.	Hazelwood	Missouri	63042	United States
Mallinckrodt PLC	SpecGx LLC	385 Marshall Ave.	Webster Groves	Missouri	63119	United States
Mayne Pharma Commercial LLC	Mayne Pharma Commercial LLC	3310 Benson Dr. Suite 401	Raleigh	North Carolina	27609	United States
McKesson Corporation	McKesson Corporation	6555 State Highway 161	Irving	Texas	75039	United States

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McKesson Corporation	McKesson Medical- Surgical, Inc.	9954 Maryland Dr. Suite 4000	Richmond	Virginia	23228	United States
McKesson Corporation	Northstar Rx, LLC	4835 Crumpler Road	Memphis	Tennessee	38141-8300	United States
Medefil, Inc	Medefil, Inc	250 Windy Point Drive	Glendale Heights	Illinois	60139	United States
Medexus Pharma, Inc.	Medexus Pharma, Inc.	29 N. Wacker Drive, Suite 704	Chicago	Illinois	60606	United States
Medimetriks Pharmaceuticals, Inc.	Medimetriks Pharmaceuticals, Inc.	383 Route 46 West	Fairfield	New Jersey	07004	United States
Meiyume	Meiyume	1359 Broadway 17th Floor	New York	New York	10018	United States
Meiyume	Lornamead Inc.	175 Cooper Avenue	Tonawanda	New York	14150	United States
Melinta Therapeutics LLC	Melinta Therapeutics LLC	300 TriState International, Suite 272	Lincolnshire	Illinois	60069	United States
Merck & Co., Inc.	Merck & Co., Inc.	126 East Lincoln Ave	Rahway	New Jersey	07065	United States
Merck & Co., Inc.	Intervet, Inc., doing business as Merck Animal Health	2 Giralda Farms	Madison	New Jersey	07940	United States
Merck & Co., Inc.	Merck Sharp & Dohme LLC	126 East Lincoln Ave. P.O. Box 2000	Rahway	New Jersey	07065	United States
Merz Pharmaceuticals, LLC	Merz Pharmaceuticals, LLC	6601 Six Forks Road, Suite 430	Raleigh	North Carolina	27615	United States
Mikart, LLC	Mikart, LLC	1750 Chatahoochee Ave NW	Atlanta	Georgia	30318	United States
Mission Pharmacal Company	Mission Pharmacal Company	P.O. Box 786099	San Antonio	Texas	78278-6099	United States
Mission Pharmacal Company	BioComp Pharma, Inc.	P.O. Box 786099	San Antonio	Texas	78278-6099	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Mitsubishi Tanabe Pharma America	Mitsubishi Tanabe Pharma America	525 Washington Blvd Ste 400	Jersey City	New Jersey	07310	United States
Morton Grove Pharmaceuticals, Inc.	Morton Grove Pharmaceuticals, Inc.	6451 Main Street	Morton Grove	Illinois	60053	United States
Morton Grove Pharmaceuticals, Inc.	Wockhardt USA LLC	20 Waterview Blvd., 3rd Floor	Parsippany	New Jersey	07054	United States
Mylan Inc.	Mylan Inc.	1000 Mylan Boulevard	Canonsburg	Pennsylvania	15317	United States
Mylan Inc.	Alaven Pharmaceuticals LLC	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Alphapharm Pty Ltd	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	DPT Laboratories LTD (DD)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	DPT Laboratories LTD (JS)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Greenstone LLC	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Meda Pharmaceuticals, Inc.	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Institutional Galway	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Reg Affs				
Mylan Inc.	Mylan Institutional Inc. (IL)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Institutional Inc. (TX)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Institutional LLC	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (1606- 1609JP)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (20/21JP)	Reg Affs 3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Dec Affe				
Mylan Inc.	Mylan Laboratories Limited (BL)	Reg Affs 3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (F4/F12OSD)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (H12/H13OSD)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Mylan Inc.	Mylan Laboratories Limited (OTL)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (SF)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (SFF)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Laboratories Limited (SPD)	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Pharmaceuticals, Inc.	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Specialty L.P.	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Mylan Technologies, Inc.	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Pfizer Pharmaceuticals LLC (Barceloneta)	3711 Collins Ferry Road, Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Pfizer Pharmaceuticals LLC (Vega Baja)	3711 Collins Ferry Road, Reg Affs	Morgantown	West Virginia	26505	United States

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Mylan Inc.	Viatris Specialty LLC	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Mylan Inc.	Wallace Pharmaceuticals, Inc.	3711 Collins Ferry Road	Morgantown	West Virginia	26505	United States
		Reg Affs				
Myovant Sciences LLC	Myovant Sciences LLC	2000 Sierra Point Pkwy	Brisbane	California	94005	United States
Myovant Sciences LLC	Myovant Sciences, Inc.	2000 Sierra Point Parkway	Brisbane	California	94005	United States
Nabriva Therapeutics US, Inc.	Nabriva Therapeutics US, Inc.	414 Commerce Drive Suite 120	Fort Washington	Pennsylvania	19034	United States
Neos Therapeutics, Inc.	Neos Therapeutics, Inc.	2940 N State Highway 360 Ste 400	Grand Prairie	Texas	75050-6424	United States
Neos Therapeutics, Inc.	Neos Therapeutics Brand LLC	2940 N. State Highway 360 Suite 400	Grand Prairie	Texas	75050	United States
Neos Therapeutics, Inc.	Neos Therapeutics LP	2940 N State Highway 360 Ste 400	Grand Prairie	Texas	75050-6424	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation	4500 12th Street Ext	West Columbia	South Carolina	29172-3025	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 1	840 S. 67th Avenue	Phoenix	Arizona	85043	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 2	78 Spruce Street	Murray	Kentucky	42071	United States

Parent Company	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Name						
Neurocrine	Neurocrine	12780 El Camino	San Diego	California	92130	United States
Biosciences, Inc.	Biosciences, Inc.	Real				
New World Imports	New World Imports	160 Athens Way	Nashville	Tennessee	37228	United States
Norbrook	Norbrook	Carnbane Industrial	Newry, County	N/A	BT35 6QQ	United Kingdom
Laboratories Limited	Laboratories Limited	Estate	Down			
Norbrook Laboratories Limited	Norbrook, Inc.	9733 Loiret Blvd	Lenexa	Kansas	66219	United States
Nostrum	Nostrum	705 East Mulberry	Bryan	Ohio	43506	United States
Laboratories, Inc.	Laboratories, Inc.	Street				
Novartis Group	Novartis Group	59 Route 10	East Hanover	New Jersey	07936	United States
Companies	Companies					
Novartis Group Companies	Eon Labs, Inc.	4700 Sandoz Drive	Wilson	North Carolina	27893	United States
Novartis Group	Fougera	60 Baylis Road	Melville	New York	11747	United States
Companies	Pharmaceuticals Inc.					
Novartis Group	Novartis	1 Health Plaza	East Hanover	New Jersey	07936-1016	United States
Companies	Pharmaceuticals Corporation					
Novartis Group	Sandoz Inc.	100 College Road	Princeton	New Jersey	08540	United States
Companies		West				
Noven Pharmaceuticals, Inc.	Noven Pharmaceuticals, Inc.	11960 SW 144th St	Miami	Florida	33186	United States
Noven Pharmaceuticals, Inc.	Hisamitsu America, Inc.	100 Campus Drive Suite 117	Florham Park	New Jersey	07932	United States
Noven Pharmaceuticals, Inc.	Noven Therapeutics, LLC	11960 SW 144th St	Miami	Florida	33186-6109	United States
Noven Pharmaceuticals, Inc.	Noven Therapeutics, LLC dba Grove Pharmaceuticals	11960 SW 144th St	Miami	Florida	33186	United States
Novo Nordisk Inc.	Novo Nordisk Inc.	800 Scudders Mill Road	Plainsboro	New Jersey	08536	United States
Novo Nordisk Inc.	Novo Nordisk Pharma Inc	800 Scudders Mill Rd	Plainsboro	New Jersey	08536-1606	United States
OCuSOFT Inc.	OCuSOFT Inc.	30444 SW FWY Building B	Rosenberg	Texas	77471	United States

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Optinose US, Inc.	Optinose US, Inc.	1020 Stony Hill Road Suite 300	Yardley	Pennsylvania	19067	United States
OrchidPharma, Inc.	OrchidPharma, Inc.	4 Independence Way Ste 125	Princeton	New Jersey	08540	United States
OrchidPharma, Inc.	Orchid Pharma Ltd.	313 Valluvar Kottam High Rd	Nungambakkam	Tamil Nadu	600 034	India
Orexo US, Inc.	Orexo US, Inc.	150 Headquarters Plaza	Morristown	New Jersey	07960	United States
Organon LLC	Organon LLC	30 Hudson Street	Jersey City	New Jersey	07301	United States
Orion Corporation	Orion Corporation	Orionintie 1	Espoo	N/A	02200	Finland
Otsuka America Pharmaceutical, Inc.	Otsuka America Pharmaceutical, Inc.	508 Carnegie Center	Princeton	New Jersey	08540	United States
Padagis US LLC	Padagis US LLC	1251 Lincoln Road	Allegan	Michigan	49010	United States
Paratek Pharmaceuticals	Paratek Pharmaceuticals	75 Park Plaza	BOSTON	Massachusetts	02116	United States
PARI Respiratory Equipment, Inc.	PARI Respiratory Equipment, Inc.	2412 Pari Way	Midlothian	Virginia	23112	United States
PARI Respiratory Equipment, Inc.	Genericus, Inc.	4860 Cox Road Suite 200	Glen Allen	Virginia	23060	United States
Pegasus Laboratories, Inc.	Pegasus Laboratories, Inc.	8809 Ely Road	Pensacola	Florida	32514	United States
Perrigo Company	Perrigo Company	515 Eastern Avenue	Allegan	Michigan	49010	United States
Perrigo Company	HRA Pharma America	36 Cattano Ave Suite 400	Morristown	New Jersey	07960	United States
Perrigo Company	L. Perrigo Company	515 Eastern Avenue	Allegan	Michigan	49010	United States
Perrigo Company	Perrigo Direct Inc.	725 Highway 74 S	Peachtree	Georgia	30269	United States
Perrigo Company	Perrigo New York, Inc.	1625 Bathgate Avenue	Bronx	New York	10457	United States

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Perrigo Company	PMI Branded Pharmaceuticals, Inc.	515 Eastern Avenue	Allegan	Michigan	49010	United States
Petros Pharmaceuticals, Inc.	Petros Pharmaceuticals, Inc.	1185 Avenue of the Americas Suite 249	New York City	New York	10036	United States
Petros Pharmaceuticals, Inc.	Metuchen Pharmaceuticals, LLC	200 US Highway 9 Suite 500	Manalapan Township	New Jersey	07726	United States
Pfizer Inc.	Pfizer Inc.	235 East 42nd Street MS 219-5	New York	New York	10017	United States
Pfizer Inc.	Array Biopharma Inc.	3200 Walnut Street	Boulder	Colorado	80301	United States
Pfizer Inc.	Biohaven Pharmaceuticals Inc.	234 Church St	New Haven	Connecticut	06510	United States
Pfizer Inc.	Global Blood Therapeutics Inc	180 Oyster Point Blvd	South San Francisco	California	94080	United States
Pfizer Inc.	Hospira	275 N. Fields Drive	Lake Forest	Illinois	60045	United States
Pharmaceutical Associates, Inc.	Pharmaceutical Associates, Inc.	1700 Perimeter Road	Greenville	South Carolina	29605	United States
Pharmasphere, Inc.	Pharmasphere, Inc.	120 Route 17 North	Paramus	New Jersey	07652	United States
Pharmasphere, Inc.	US Vet, Inc.	120 Route 17 North	Paramus	New Jersey	07652	United States
Pharmasphere, Inc.	WG Critical Care LLC	120 Route 17 North	Paramus	New Jersey	07652	United States
Pharming Healthcare Inc.	Pharming Healthcare Inc.	10 Independence Blvd. 4th Floor	Warren	New Jersey	07059	United States
Preferred Pharmaceuticals Inc	Preferred Pharmaceuticals Inc	1250 North Lakeview Ave Unit O	Anaheim	California	92807	United States
Premier Dental Products Company	Premier Dental Products Company	1710 ROMANO DR.	Plymouth Meeting	Pennsylvania	19462	United States
Prestige Consumer Healthcare, Inc.	Prestige Consumer Healthcare, Inc.	660 White Plains Road,2nd Floor	Tarrytown	New York	10591	United States

Parent Company	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Name						
Prestige Consumer	C.B. Fleet Company,	660 White Plains	Tarrytown	New York	10591	United States
Healthcare, Inc.	Incorporated	Road,2nd Floor				
Prestige Consumer	DenTek Oral Care, Inc.	660 White Plains	Tarrytown	New York	10591	United States
Healthcare, Inc.		Road,2nd Floor				
Prestige Consumer	Insight	660 White Plains	Tarrytown	New York	10591	United States
Healthcare, Inc.	Pharmaceuticals LLC	Road,2nd Floor				
Prestige Consumer	Medtech Products	660 White Plains	Tarrytown	New York	10591	United States
Healthcare, Inc.	Inc.	Road, 2nd Floor				
Primus	Primus	7373 N Scottsdale	Scottsdale	Arizona	85253	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.	Rd. B-200				
Professional	Professional	400 Chestnut Ridge	Woodcliff Lake	New Jersey	07677	United States
Disposables	Disposables	Rd				
International Inc.	International Inc.					
Provell	Provell	1801 Horseshoe	Honey Brook	Pennsylvania	19344	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Pike - Suite 1				
Puma Biotechnology	Puma Biotechnology	10880 Wilshire	Los Angeles	California	90024	United States
•		Boulevard				
		Suite 2150				
PuraCap	PuraCap	517 Route 1	Iselin	New Jersey	08830	United States
International, LLC	International, LLC					
		Suite 4002				
PuraCap	Epic Pharma, LLC	227-15N	Laurelton	New York	11413	United States
International, LLC		Conduit Ave.				
PuraCap	PuraCap Caribe	Carr 698 km 0.8	Bo Mameyal	Puerto Rico	00646	United States
International, LLC			Dorado			
PuraCap	PuraCap Laboratories	87 Glen Cove Road	Greenvale	New York	11548	United States
International, LLC	LLC dba Blu					
,	Pharmaceuticals	Unit 3A				
PuraCap	PuraCap	517 Route 1	Iselin	New Jersey	08830	United States
International, LLC	Pharmaceutical, LLC			,		
- / -	, -	Suite 4002				
Purdue Pharma L.P.	Purdue Pharma L.P.	One Stamford	Stamford	Connecticut	06901	United States
		Forum				
Purdue Pharma L.P.	Adlon Therapeutics,	One Stamford	Stamford	Connecticut	06901	United States
	LP	Forum				

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Purdue Pharma L.P.	Avrio Health L.P.	One Stamford Forum	Stamford	Connecticut	06901	United States
Purdue Pharma L.P.	Purdue Pharmaceuticals L.P.	4701 Purdue Drive	Wilson	North Carolina	27893	United States
Purdue Pharma L.P.	Rhodes Pharmaceuticals L.P.	498 Washington Street	Coventry	Rhode Island	02816	United States
QOL Medical, LLC	QOL Medical, LLC	3405 Ocean Drive	Vero Beach	Florida	32963	United States
Quest Products	Quest Products	8201 104th Street	Pleasant Prairie	Wisconsin	53158	United States
Quest Products	Summit Pharmaceuticals	1406 W. Victory Lane	Phoenix	Arizona	85027	United States
RB Health (US) LLC	RB Health (US) LLC	399 Interpace Parkway	Parsippany	New Jersey	07054	United States
Recordati Rare Diseases, Inc.	Recordati Rare Diseases, Inc.	440 Route 22 East	Bridgewater	New Jersey	08807	United States
Regeneron Pharmaceuticals, Inc	Regeneron Pharmaceuticals, Inc	777 Old Saw Mill River Rd	Tarrytown	New York	10591	United States
Regeneron Pharmaceuticals, Inc	Regeneron Healthcare Solutions, Inc	745 Old Saw Mill River Rd	Tarrytown	New York	10591	United States
Regeneron Pharmaceuticals, Inc	Regeneron Ireland DAC	Raheen Business Park	Limerick	N/A	V94	Ireland
Rhythm Pharmaceuticals, Inc.	Rhythm Pharmaceuticals, Inc.	222 Berkeley Street 12th Floor	Boston	Massachusetts	02116	United States
Rising Pharma Holdings, Inc.	Rising Pharma Holdings, Inc.	2 Tower Center Boulevard	East Brunswick	New Jersey	08816	United States
Rising Pharma Holdings, Inc.	Casper Pharma LLC	2 Tower Center Boulevard, Suite 1101	East Brunswick	New Jersey	08816	United States
Rivopharm SA	Rivopharm SA	Centro Insema	Manno	N/A	6928	Switzerland
Roche Holdings	Roche Holdings	9115 Hague Road	Indianapolis	Indiana	46250	United States
Roche Holdings	Genentech, Inc.	Hoffman-La Roche Inc. 1 DNA Way	South San Francisco	California	94080-4990	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
RVL Pharmaceuticals, Inc.	RVL Pharmaceuticals, Inc.	400 Crossing Blvd	Bridgewater	New Jersey	08807	United States
Safecor Health, LLC	Safecor Health, LLC	4060 BUSINESS PARK DRIVE	COLUMBUS	Ohio	43204	United States
Sagent Pharmaceuticals	Sagent Pharmaceuticals	1901 N. Roselle Road Suite 450	Schaumburg	Illinois	60195	United States
Sagent Pharmaceuticals	SterRx, LLC	141 Idaho Road	Plattsburgh	New York	12903	United States
Sanofi-Aventis US LLC.	Sanofi-Aventis US LLC.	55 Corporate Drive	Bridgewater	New Jersey	08807	United States
Sanofi-Aventis US LLC.	Chattem, Inc.	1715 West 38th St.	Chattanooga	Tennessee	37409	United States
Sanofi-Aventis US LLC.	Genzyme Corporation	450 Water Street	Cambridge	Massachusetts	02141	United States
Sanofi-Aventis US LLC.	Kadmon Holdings	450 East 29th Street	New York	New York	10016	United States
Scilex Holding Company	Scilex Holding Company	960 San Antonio Road, Suite 100	Palo Alto	California	94303	United States
Scilex Holding Company	Scilex Pharmaceuticals Inc.	960 San Antonio Road, Suite 100	Palo Alto	California	94303	United States
SCYNEXIS, Inc.	SCYNEXIS, Inc.	1 Evertrust Plaza 13th Floor	Jersey City	New Jersey	07302	United States
Seagen	Seagen	21823 30th Drive Southeast	Bothell	Washington	98021	United States
Sebela Pharmaceuticals Inc.	Sebela Pharmaceuticals Inc.	645 Hembree Pkwy Suite I	Roswell	Georgia	30076	United States
Sebela Pharmaceuticals Inc.	Affordable Pharmaceuticals LLC	60 Columbian St. West Suite 200 P.O. Box 850253	Braintree	Massachusetts	02185-0253	United States
Sebela Pharmaceuticals Inc.	Braintree Laboratories Inc.	60 Columbian Street West P.O. Box 850929	Braintree	Massachusetts	02185-0929	United States
Secura Bio	Secura Bio	1995 Village Center Circle, Suite 128	Las Vegas	Nevada	89134	United States
Shionogi Inc.	Shionogi Inc.	300 Campus Dr.	Florham Park	New Jersey	07932	United States

Parent Company	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Name						
SigmaPharm	SigmaPharm	3375 Progress	Bensalem	Pennsylvania	19020	United States
Laboratories LLC	Laboratories LLC	Drive				
Slate Run	Slate Run	277 W Nationwide	Columbus	Ohio	43215	United States
Pharmaceuticals, LLC	Pharmaceuticals, LLC	Blvd., Suite 260				
Smith & Nephew, Inc.	Smith & Nephew, Inc.	5600 Clearfork	Ft. Worth	Texas	76107	United States
(Smith & Nephew	(Smith & Nephew	Main St.				
Biotherapeutics)	Biotherapeutics)					
		Suite 600				
Societal CDMO, Inc.	Societal CDMO, Inc.	1 East Uwchlan	Exton	Pennsylvania	19341-1282	United States
		Avenue				
		Suite 112				
Societal CDMO, Inc.	Societal CDMO	1300 Gould Drive	Gainesville	Georgia	30504	United States
	Gainesville, LLC					
Societal CDMO, Inc.	Societal CDMO San	6828 Nancy Ridge	San Diego	California	92121	United States
	Diego, LLC	Drive, Suite 100	_			
Spirit	Spirit	2004-02 Orville	Ronkonkoma	New York	11779	United States
Pharmaceuticals LLC	Pharmaceuticals LLC	Drive North				
Sprout	Sprout	4350 Lassiter at	Raleigh	North Carolina	27609	United States
Pharmaceuticals	Pharmaceuticals	North Hills Ave				
		#260				
Stallergenes Greer	Stallergenes Greer	639 Nuway Circle	Lenoir	North Carolina	28645	United States
		NE				
Stallergenes Greer	Stallergenes Greer	639 Nuway Circle	Lenoir	North Carolina	28645	United States
		NE				
Sunovion	Sunovion	84 Waterford Dr	Marlborough	Massachusetts	01752-7010	United States
Pharmaceuticals Inc.	Pharmaceuticals Inc.					
Supernus	Supernus	9715 Key West	Rockville	Maryland	20850	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.	Avenue				
Swedish Orphan	Swedish Orphan	SE-112 76	Stockholm	N/A	02451	Sweden
Biovitrum AB (Sobi	Biovitrum AB (Sobi					
AB)	AB)					
, Swedish Orphan	, AkaRx, Inc.	240 Leigh Farm Rd	Durham	North Carolina	27707	United States
Biovitrum AB (Sobi						
AB)		Suite 245				

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Swedish Orphan Biovitrum AB (Sobi AB)	Sobi Inc	77 4th Avenue 3rd Floor	Waltham	Massachusetts	02451	United States
Taiho Oncology, Inc.	Taiho Oncology, Inc.	101 Carnegie Center, Suite 101	Princeton	New Jersey	08540	United States
Takeda Pharmaceuticals America, Inc.	Takeda Pharmaceuticals America, Inc.	95 Hayden Avenue	Lexington	Massachusetts	02421	United States
Takeda Pharmaceuticals America, Inc.	Baxalta Incorporated	95 Hayden Ave.	Lexington	Massachusetts	02421	United States
Takeda Pharmaceuticals America, Inc.	Dyax Corp	95 Hayden Ave.	Lexington	Massachusetts	02421	United States
Takeda Pharmaceuticals America, Inc.	Millennium Pharmaceuticals, Inc. (d/b/a Takeda Oncology)	40 Lansdowne Street	Cambridge	Massachusetts	02139	United States
Tec Laboratories, Inc.	Tec Laboratories, Inc.	7100 Tec Labs Way SW	Albany	Oregon	97321	United States
TerSera Therapeutics LLC	TerSera Therapeutics LLC	520 Lake Cook Road, Suite 500	Deerfield	Illinois	60015	United States
Teva Pharmaceuticals USA, Inc.	Teva Pharmaceuticals USA, Inc.	1090 Horsham Rd	North Wales	Pennsylvania	19454-1505	United States
Teva Pharmaceuticals USA, Inc.	Actavis Generics	400 Interpace Pkwy	Parsippany	New Jersey	07054	United States
Teva Pharmaceuticals USA, Inc.	Cephalon, Inc.	Morris Corporate Center III 400 Interpace Pkwy	Parsippany	New Jersey	07054	United States
Teva Pharmaceuticals USA, Inc.	Teva Neuroscience Inc.	11100 Nail Ave	Overland Park	Kansas	66221	United States
The Hain Celestial Group, Inc.	The Hain Celestial Group, Inc.	4600 Sleepytime Drive	Boulder	Colorado	80301	United States
The Mentholatum Company	The Mentholatum Company	707 Sterling Drive	Orchard Park	New York	14127	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
The Mentholatum Company	Mentholatum (China) Pharmaceuticals Co., Ltd.	The Second Industrial Estates	Sanxiang, Zhongshan	Guangdong	528463	China
The Mentholatum Company	Rohto Pharmaceutical Co. Ltd.	7-3 Yumegaoka, Ige	Mie	N/A	518-0131	Japan
The Procter & Gamble Company	The Procter & Gamble Company	1 Procter & Gamble Plaza	Cincinnati	Ohio	45202	United States
The Ritedose Corporation (TRC)	The Ritedose Corporation (TRC)	1 Technology Circle	Columbia	South Carolina	29203	United States
The Ritedose Corporation (TRC)	Ritedose Pharmaceuticals, LLC	1 Technology Circle	Columbia	South Carolina	29203	United States
Thea Pharma Inc	Thea Pharma Inc	420 Bedford Street, Suite 150	Lexington	Massachusetts	02420	United States
TOLMAR, Inc.	TOLMAR, Inc.	701 Centre Avenue	Fort Collins	Colorado	80526	United States
Tower Laboratories LTD.	Tower Laboratories LTD.	8 Industrial Park Road	Centerbrook	Connecticut	06409	United States
Travere Therapeutics, Inc.	Travere Therapeutics, Inc.	3661 Valley Centre Dr. Suite 300	San Diego	California	92130	United States
TRIPOINT THERAPEUTICS, LLC	TRIPOINT THERAPEUTICS, LLC	111 QUIMBY STREET Suite 9	WESTFIELD	New Jersey	07090	United States
Tris Pharma, Inc.	Tris Pharma, Inc.	2033 Route 130	Monmouth Junction	New Jersey	08852	United States
Tris Pharma, Inc.	NextWave Pharmaceuticals	2033 Route 130	Monmouth Junction	New Jersey	08852	United States
UCB Inc.	UCB Inc.	1950 Lake Park Drive	Smyrna	Georgia	30080	United States
UCB Inc.	Zogenix	1950 Lake Park Drive	Smyrna	Georgia	30080	United States
Ultragenyx Pharmaceutical, Inc.	Ultragenyx Pharmaceutical, Inc.	60 Leveroni Ct	Novato	California	94949	United States
United Therapeutics Corporation	United Therapeutics Corporation	55 TW Alexander Dr.	Durham	North Carolina	27709	United States
USWM, LLC	USWM, LLC	4441 Springdale Rd	Louisville	Kentucky	40241	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Validus Pharmaceuticals LLC	Validus Pharmaceuticals LLC	90 East Halsey Road, Suite 210	Parsippany	New Jersey	07054	United States
Veloxis Pharmaceuticals, Inc.	Veloxis Pharmaceuticals, Inc.	2000 Regency Pkwy Ste 500	Cary	North Carolina	27518	United States
Vertex Pharmaceuticals Incorporated	Vertex Pharmaceuticals Incorporated	50 Northern Avenue	Boston	Massachusetts	02210	United States
Vi-Jon, LLC	Vi-Jon, LLC	8515 Page Ave	St. Louis	Missouri	63114	United States
Vifor Pharma, Inc.	Vifor Pharma, Inc.	100 Cardinal Way	Redwood City	California	94063	United States
Virbac Corporation	Virbac Corporation	1301 Solana Blvd Suite 2400 Building 2	Westlake	Texas	76262	United States
Virbac Corporation	Virbac AH, Inc	1301 Solana Blvd Suite 2400 Building 2	Westlake	Texas	76262	United States
VistaPharm, Inc	VistaPharm, Inc	7325 Ulmerton Rd	Largo	Florida	33771	United States
Vitruvias Therapeutics Inc	Vitruvias Therapeutics Inc	778 N DEAN RD STE 600	Auburn	Alabama	36830	United States
VIVUS LLC	VIVUS LLC	900 E Hamilton Ave Ste 550	Campbell	California	95008-0643	United States
WellSpring Pharmaceutical Corporation	WellSpring Pharmaceutical Corporation	5911 N. Honore Avenue Suite 211	Sarasota	Florida	34243	United States
West Therapeutic Development, LLC	West Therapeutic Development, LLC	1033 Skokie Boulevard, Suite 620	Northbrook	Illinois	60062	United States
Winder Laboratories LLC	Winder Laboratories LLC	716 Patrick Industrial Lane	Winder	Georgia	30680-8333	United States
Wisconsin Pharmacal Company, LLC	Wisconsin Pharmacal Company, LLC	1 Pharmacal Way	Jackson	Wisconsin	53037	United States
Wisconsin Pharmacal Company, LLC	Lake Consumer Products, Inc. (subsidiary of Wisconsin Pharmacal)	1 Pharmacal Way	Jackson	Wisconsin	53037	United States

Parent Company	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Name						
Xeris	Xeris	180 N.LaSalle St	Chicago	Illinois	60601	United States
Pharmaceuticals, Inc.	Pharmaceuticals, Inc.					
XGen	XGen	300 Daniel Zenker	Horseheads	New York	14845	United States
Pharmaceuticals DJB,	Pharmaceuticals DJB,	Drive				
Inc.	Inc.					
Xiromed	Xiromed	180 Park Ave	Florham Park	New York	07932	United States
Xiromed	Exeltis, Inc	180 Park Ave	Florham Park	New Jersey	07932	United States
Xspire Pharma LLC.	Xspire Pharma LLC.	119 Marketridge Drive Suite D-2	Ridgeland	Mississippi	39157	United States
Xspire Pharma LLC.	WraSer Pharmaceuticals	119 Marketridge Drive Suite D	Ridgeland	Mississippi	39157	United States
Xttrium Laboratories, Inc.	Xttrium Laboratories, Inc.	1200 E. Business Center Dr	Mount Prospect	Illinois	60056	United States
ZO Skin Health Inc.	ZO Skin Health Inc.	9685 Research Drive	Irvine	California	92618	United States
Zoetis	Zoetis	One Pfizer Way	Lee's Summit	Missouri	64081	United States
Zydus Pharmaceuticals USA Inc	Zydus Pharmaceuticals USA Inc	73 Route 31 North	Pennington	New Jersey	08534	United States
Zydus Pharmaceuticals USA Inc	Sentynl Therapeutics, Inc.	420 Stevens Ave Suite 200	Solana Beach	California	92075	United States
Zydus Pharmaceuticals USA Inc	Viona Pharmaceuticals Inc.	20 Commerce Drive, Suite 340	Cranford	New Jersey	07016	United States

## **II.** Contact Information

The primary contact person for MED-Project is:

Dr. Victoria Travis, PharmD, MS, MBA National Program Director MED-Project LLC 4096 Piedmont Ave Unit 174 Oakland, CA 94611 Phone: 1 (833) 633-7765 Fax: 1 (866) 633-1812 sanmateocounty@med-project.org

## **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<sup>1</sup>.

**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 stations, and Department staff that can be reached by callers at a toll-free number and/or by email at sanmateocounty@med-project.org.

**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.

<sup>&</sup>lt;sup>1</sup> 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.

**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.

**On-Demand Collection Service** is a service model where Unwanted Medicine Kiosk Drop-Off Site staff manage removal and packaging of full Unwanted Medicine inner liners prior to transfer to a Carrier for transport to a reverse distributor.

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.

**Scheduled Collection Service** is a service model where MED-Project provides for a Vendor service technician to help prepare Unwanted Medicine inner liners at Unwanted Medicine Kiosk Drop-Off Sites for transfer to a Carrier for transport to a reverse distributor.

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.

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 Medicine<sup>2</sup>

For the purposes of the Plan, "Unwanted Medicine" includes all materials identified as "Covered Drugs" under Ordinance § 4.116.020(D) that qualify as "Unwanted Covered Drug[s]" under Ordinance § 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.

<sup>&</sup>lt;sup>2</sup> 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.

# 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 continues to perform outreach via annual notification letters to potential Kiosk Drop-Off Sites. During the last round, MED-Project notified 25 sites with a licensed pharmacy of the opportunity to participate as a Kiosk Drop-Off Site.

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 continues to satisfy the Service Convenience Goals through executed agreements with Kiosk Drop-Off Site Hosts. If there is a change and the number of Kiosk Drop-Off Sites falls below the Service Convenience Goals, 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.3 for details on how MED-Project satisfies 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 has established 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 has established a minimum of five (5) Kiosk Drop-Off Sites in each Supervisorial District.

MED-Project meets Service Convenience Goals by providing Kiosk Drop-Off Sites at over 50 locations as well as Mail-Back Services that are available 24 hours a day, every day of the year, via the MED-Project Website and Call Center. MED-Project has analyzed the populated areas in the County and has determined that the Service Convenience Goal is currently being met by MED-Project via the placement of Kiosk Drop-Off Sites across the County. MED-Project operates kiosks within five miles of all incorporated cities within San Mateo County as shown in the map below in Figure 1. MED-Project understands populated areas to be defined as incorporated cities for the purpose of implementation. MED-Project has established Kiosk Drop-Off Sites within five miles of all incorporated cities and within five miles of all incorporated towns, where possible.

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. If the number of Kiosk Drop-Off Sites falls below the Service Convenience Goals, MED-Project will seek to obtain additional agreements with Kiosk Drop-Off Site Hosts. Supplemental services such as Mail-Back Distribution Locations and/or Take-Back Events would then be decreased accordingly upon meeting the Service Convenience Goals.

Standard Mail-Back Services are available to all Residents including disabled and home-bound Residents upon request and are 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 outlined above, MED-Project, as required by the Ordinance, will coordinate with all other approved stewardship plans to operate Kiosk Drop-Off Sites within County-owned pharmacies. See Coordination Section XVI. MED-Project operates a Kiosk Drop-Off site at the County-owned facility.

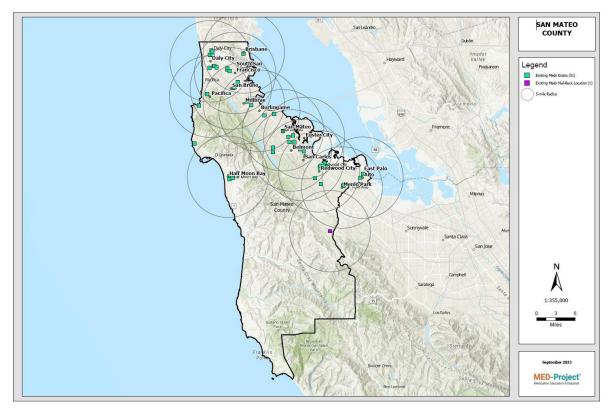


Figure 1: Existing Kiosk Drop-Off Sites and Mail-Back Distribution Locations

#### 4. Services

MED-Project assesses performance, gauges feedback, and revises its approach as appropriate. MED-Project continues outreach to organizations that may be available as future Kiosk Drop-Off Sites on an annual basis.

The Plan is implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites and/or Mail-Back Distribution Locations, if needed to meet the Service Convenience Goals. Over the course of ongoing implementation, additional Kiosk Drop-Off Sites will be established to the extent that additional eligible LEAs and/or DEA-registered collector pharmacies agree to participate, and contracts can be executed with such entities. MED-Project will establish Mail-Back Distribution Locations, when and if the Service Convenience Goals are not met. 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 do not provide kiosk collection for Pre-filled Injector Products, Injector Mail-Back Services for Pre-filled Injector Products are available through the Call Center and MED-Project Website for all Residents.

MED-Project will inform the County of changes according to and as required by the Ordinance.

### B. Kiosk Drop-Off Sites

Kiosk Drop-Off Sites are strategically placed throughout the County in order to best meet the Service Convenience Goals established by the Ordinance. All Kiosk Drop-Off Sites will 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 continues outreach to potential Kiosk Drop-Off Sites that are not participating in the Program via annual notification letters sent to nonparticipating or new Retail Pharmacies, according to requirements in Ordinance § 4.116.030(e)(2).

MED-Project will establish Mail-Back Distribution Locations in any Supervisorial District if 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.

MED-Project has established 52 kiosks at 51 Kiosk Drop-Off Sites that are currently participating in the Program as shown in Figure 1.

#### 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) inspect the kiosk during kiosk collection service and escalate issues for maintenance as needed. The inspection includes 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 is available upon request.

Vendor responds within two to three business days of a requested maintenance service unless the requested service requires an Unplanned Event Response. See Section V.B.7.

#### 3. Kiosk Specifications

Kiosks are offered to all eligible host locations. Pursuant to § 1317.75(e), MED-Project kiosks at pharmacies are:

- Securely fastened to a permanent structure;
- 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 noncontrolled 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 (Appendix B) 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 increases the likelihood of consumer participation by providing easy access to wheelchair-bound users. The locking mechanism on the drop-slot prevents kiosk overflow once the container has reached its maximum level and is locked by the Kiosk Drop-Off Site Host. MED-Project pharmacy kiosks come with appropriate regulatory signage and instructions, including an instruction to remove personal information from any Unwanted Medicine and packaging before depositing them and language required under the DEA Rule<sup>3</sup> and by the Board of Pharmacy. Kiosk signage provides information about what is and is not accepted in the kiosk.

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

<sup>&</sup>lt;sup>3</sup> 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."

- Waterproof, tamper-evident, and tear-resistant;
- 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 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

MED-Project's Kiosk Drop-Off Site collection system follows DEA requirements for pharmacy and LEA Unwanted Medicine Kiosk Drop-Off Sites. Per these requirements:

- Kiosk Drop-Off Site employees shall hold the two keys to unlock the kiosk;
- Vendor, pharmacies, and LEAs taking part in the Plan shall keep all records required under the DEA Rule, including those required under DEA Rule §§ 1304 and 1317.35;
- Inner liners provided in the kiosk are opaque to prevent visual recognition of the contents; and
- Each inner liner and box provided by Vendor is pre-paid and pre-addressed for transport and disposal.

#### a. Pharmacy Kiosk Inner Liner Handling and Disposal

The DEA Rule limits inner liner access to employees of the collector and requires two employees to seal the inner liner at once following its removal from the pharmacy kiosk's permanent outer container. DEA Rule § 1317.60(b), (c). DEA Rule § 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. DEA Rule § 1317.60(c). DEA Rule § 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk.

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

#### b. LEA Kiosk Inner Liner Handling and Disposal

Any collection of controlled substances by LEAs will be consistent with the LEA's standard procedures for transferring illicit controlled substances. DEA Rule § 1317.35. 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 LEA's recordkeeping requirements for illicit controlled substances evidence under DEA Rule § 1317.35.

Any collected Unwanted Medicine should 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. DEA Rule § 1317.35. Collected Unwanted Medicine should 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. DEA Rule § 1317.35.

#### 5. Collection Methods

A Kiosk Drop-Off Site Host may choose to participate in the program via either the Scheduled Collection Service method or On-Demand Collection Service method. For both methods, MED-Project provides for the collection, transport, and disposal of Unwanted Medicine at no cost to the Kiosk Drop-Off Site.

If a Kiosk Drop-Off Site Host elects to participate via the On-Demand Collection Service method, the Kiosk Drop-Off Site employees shall prepare the inner liner for shipment. The On-Demand Collection Service method enables a Kiosk Drop-Off Site Host to directly control the timing for servicing the kiosk and to seal the liner for packaging and transport at a time of its choosing. The Kiosk Drop-Off Site employees can schedule Carrier to pick up the packaged inner liner or can offer the packaged inner liner during a regular Carrier pick-up. This method enables the Kiosk Drop-Off Site to avoid disruptions to operations that may result from Vendor-scheduled visits or storage limitations.

If a Kiosk Drop-Off Site Host elects to participate via the Scheduled Collection Service method, a Service Technician will regularly come to the Kiosk Drop-Off Site to help prepare the inner liner for shipment and disposal. Kiosk Drop-Off Sites that are taking part in the Scheduled Collection Service method will have regular year-round scheduled time for pick-up by Carrier based on the specific location's business hours and volume of collected medications.

#### 6. Kiosk Service

When servicing a kiosk at a Kiosk Drop-Off Site, two On-Demand Collection Service Kiosk Drop-Off Site employees, or a Service Technician under the supervision of two Scheduled Collection Service Kiosk Drop-Off Site employees following instructions provided by Vendor, will:

- Check the kiosk for any damage.
- Remove the inner liner and box from the kiosk and seal them at once following procedures meeting all DEA requirements.

- Replace the removed inner liner and box with a replenishment inner liner and box provided by Vendor.
- Match the unique identifier of the inner liner to the tracking number on the shipping label.
- Package the inner liner for transport.
- Prepare the materials for shipment and perform applicable pre-transportation functions following the DOT Hazardous Materials Regulations ("HMR").
- Schedule a pick-up from Carrier to be completed within a few business days or offer the package holding the sealed inner liner for pick-up by routine Carrier service at the Unwanted Medicine Kiosk Drop-Off Site.

If the package with the sealed inner liner is prepared before Carrier pick-up, the 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.

#### 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 and relates to the Kiosk Drop-Off Site requesting an expedited service for a kiosk filling up, the Program is designed to provide services within 48 hours from the time such a request is made.

Finally, 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 and/or finalize the locations and dates of any Take-Back Events once contracts with overseeing LEAs have been executed.

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.C.

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. 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 will pay all administrative and operational costs and fees associated with the Take-Back Events.

### D. Disposal of Unwanted Medicine

Vendor and Carrier shall manage the Unwanted Medicine from Scheduled Collection Services from 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.

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. On-Demand Collection Services Kiosk Drop-Off Sites will manage sealed inner liners as described in Section V.B.4(b).

MED-Project will dispose of Unwanted Medicine at permitted Hazardous Waste Incinerators, and Medical Waste Incinerators as identified in Section X and as approved in MED-Project's previous plan approved by the County on January 16, 2020 (County approval included as Appendix C).

### E. Mail-Back Services for Unwanted Medicine

In addition to established Kiosk Drop-Off Sites, MED-Project offers comprehensive Mail-Back Services throughout the County for all Residents. Based on MED-Project's experience operating stewardship programs in San Mateo County and other jurisdictions, Mail-Back Services provide a year-round option for Residents to obtain Mail-Back Packages and educational materials promoting the safe storage and proper disposal of Unwanted Medicine. Because Mail-Back Services are available year-round, Residents can obtain Mail-Back Packages whenever they need to dispose of Unwanted Medicine.

MED-Project provides three types of Mail-Back Services that are available through the Call Center and MED-Project Website:

- Standard Mail-Back Services for all 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 all Residents as described in Section V.E.3.

#### 1. Standard Mail-Back Services for Unwanted Medicine

MED-Project provides Standard Mail-Back Services at no cost to all Residents including disabled and home-bound Residents via the Call Center and/or MED-Project Website. The pre-paid shipping label directs 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 are:

- 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 offers all Residents including disabled and home-bound Residents Injector Mail-Back Services via the Call Center and/or MED-Project Website. The pre-paid shipping label directs the Injector Mail-Back Package to the facility identified in Section X. An instruction sheet is 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 D for a sample package and package specifications.

#### 3. Inhaler Mail-Back Services for Inhalers

For inhalers, MED-Project offers all Residents including disabled and home-bound Residents Inhaler Mail-Back Services via the Call Center and/or MED-Project Website. The pre-paid shipping label directs the Inhaler Mail-Back Package to the facility identified in Section X. An instruction sheet is 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 D for sample package specifications.

#### 4. Mail-Back Package Availability

All Residents including 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 are provided Mail-Back Packages complying with DEA requirements, if applicable.

If a Supervisorial District has fewer than the required number of signed agreements from Kiosk Drop-Off Site Hosts, then MED-Project will supplement Kiosk Drop-Off Sites by establishing Mail-Back Distribution Locations for the dissemination of Standard Mail-Back Packages until the Service Convenience Goals are met. If needed, 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 and Inhaler Mail-Back Services are available to all Residents through the Call Center and/or MED-Project Website.

Mail-Back Packages are shipped to Residents within seven business days of their request.

#### 5. Mail-Back Package Collection and Disposal

The following general procedures are 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;

- 1. Requests by Residents are processed, and tracking numbers are logged;
- 2. Mail-Back Packages are sent to requesting Residents;
- 3. Residents place Unwanted Medicine in Mail-Back Packages per instructions;
- 4. Residents place Mail-Back Packages in mail system;
- 5. Mail-Back Packages received by facility identified in Section X and unique identifier on returned Mail-Back Packages are logged as "returned";
- 6. Mail-Back Packages are disposed of; and
- 7. 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 Packages contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in the Required Languages. Residents are directed to follow the instructions provided via Mail-Back Services. Mail-Back Services direct packages to an approved facility in accordance with their contents and packages are handled in compliance with all applicable laws.

For Standard Mail-Back Packages, upon arriving at the destruction facility, they are 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 complies with the applicable security requirements of DEA Rule § 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 is destroyed promptly.

# **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.

Goal Area	Short-Term	Long-Term
Collection	MED-Project's goal is to maintain the Service Convenience Goals through established Kiosk Drop-Off Sites with an estimated average collection of 100 pounds per Kiosk Drop-Off Site annually.	MED-Project's goal is to maintain the Service Convenience Goals through established Kiosk Drop-Off Sites and estimated average collection weight annually. In the event that MED- Project no longer meets the Service Convenience Goal, MED-Project will work with any other existing and approved program operator(s) to request and organize joint Take-Back events at least annually in areas with no access to Kiosk Drop-Off sites or Mail-Back Distribution locations within five miles of an incorporated city.
Education & Public Outreach	Starting the first full calendar year after approval of the Plan, reach 25% of the 18 years of age and over population through media outreach tactics by the end of year (1) one (i.e., end of 2024).	Achieve 50% reach of the 18 years of age and over population through media outreach tactics by the end of the second calendar year (i.e., end of 2025) after Plan approval, and beyond.
		On an annual basis, provide information to pharmacies, health care facilities, veterinarian facilities, and other interested parties, on how to obtain materials.

# **VII.** Patient Privacy

Instructions at each Kiosk Drop-Off Site 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 is no readable personally identifiable information.

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 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 are opaque rather than clear. In addition, inner liners used at Kiosk Drop-Off Sites and/or Take-Back Events are opaque rather than clear, in compliance with the DEA Rule.

## VIII. Call Center

Per Ordinance § 4.116.060, MED-Project will provide a Call Center in the Required Languages jointly with all other approved stewardship plans operating in the County. Questions from Residents will be managed through the Call Center with the support of an agent. See Coordination Section XVI.

The Call Center provides information about:

- Items that can be disposed of;
- Disposal options;
- The MED-Project Website; and
- How to request Mail-Back Packages.

To increase access to the Program for Residents, MED-Project has included dialing options for TTY and 711 services.

A sample Call Center flow is provided in Appendix F.

# IX. Training

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:

Operational procedures, including training, are the responsibility of the Kiosk Drop-Off Site Host. MED-Project supports training if agreed to with the Kiosk Drop-Off Site Host. Additionally, MED-Project provides a Help Desk to answer questions and monitor comments for participating Kiosk Drop-Off Sites.

Vendor certifies training of Unwanted Medicine Service Technicians on the following:

- Emergency Spill Response, Communication Devices, Alarm Systems;
- DOT Hazardous Materials Training meeting the requirements of 49 CFR §172.704(a), including General Awareness/Familiarization, Safety Training, Security Awareness Training, and Function-Specific training;
- DOT Hazardous Materials Training meeting the requirement in 49 CFR §172.704(a) for In-Depth Security Training (if applicable);
- Personal Protective Equipment ("PPE") Utilization;
- DEA Controlled Substance Handling Protocols;
- Health Insurance Portability and Accountability Act ("HIPAA") Requirements; and
- Occupational Safety and Health Administration ("OSHA") Bloodborne Pathogens Standards.

For more information about how entities participating in the Program will operate and comply with all applicable federal and state laws, rules, and regulations, see Section XIV.

# X. Vendor, Transporter, and Disposal Facility Information

## A. Vendor

Name	Address	Phone	Website	Туре	Penalty Record (5 years)
Covanta	190	(717) 653-		Vendor	None
Environmental	Shellyland	8882	www.covanta.		
Solutions, LLC	Road,		<u>com</u>		
	Manheim, PA 17545				
PureWay	16225 Park	(877) 765-	http://pureway.	Vendor	None
Compliance, Inc.	Ten Place,	3030	<u>com/</u>		
	Ste 830,				
	Houston, TX				
	77084				
Stericycle, Inc.	2355	(847) 367-	www.stericycl	Vendor	None
	Waukegan	5910	eenvironment		
	Road,		<u>al.com</u>		
	Bannockburn,				
	IL 60015				

### **B.** Reverse Distributor Facilities

Name	Address	Phone	Website	Туре	Penalty Record (5 years)
Covanta Environmental Solutions, LLC	2515 S. Holt Rd, Indianapolis, IN 46241	(317) 719- 6397	https://www.co vanta.com/Our - Facilities/CES- Indy	DEA Registered Collector and Reverse Distributor	None
Covanta Manheim, Pennsylvania Facility	190 Shellyland Road, Manheim, PA 17545	(717) 653- 8882	www.covanta.c om	DEA Registered Collector and Reverse Distributor	None
Stericycle, Inc. Warren, Ohio Facility	1901 Pine Avenue, SE, Warren, OH 44483	(330) 393- 0370	www.stericycle .com/service- locations/ohio/ warren	DEA Registered Collector and Reverse Distributor	None

# C. Transporters and Carriers

Name	Address	Phone	Website	Туре	Penalty Record (5 years)
Clean Harbors Environmental Services Inc.	42 Longwater Drive, Norwell, MA 02061	(781) 792- 5000	www.cleanhar bors.com	Private Carrier	1 reported case closed 12/10/20 19
Covanta Environmental Solutions Carriers II, LLC	5300 N 33rd St, Milwaukee, WI 53209	(336) 683- 0809	<u>www.covanta.</u> <u>com</u>	Private Carrier	None
Covanta Environmental Solutions dba Chesapeake Waste Solutions, LLC.	190 Shellyland Road, Manheim, PA 17545	(336) 683- 0809	<u>www.covanta.</u> <u>com</u>	Private Carrier	None
Doncin Transport, Inc.	3478 Sunnyside Rd, Manheim, PA 17545	(717) 689- 5129	None provided	Contract Carrier	None
EMS Dispatch, Inc.	316 W Mt Vernon St, Lansdale, PA 19446	(717) 689- 5129	None provided	Contract Carrier	None
Heritage Transport	1626 Research Way, Indianapolis, IN 46231	(317) 486- 2973	http://www.her itage- enviro.com/	Hazardous Waste Transporter	None
Omada Worldwide Expedite, Inc.	853 S Columbia Road, Suite 175, Plainfield, IN 46168	(317) 293- 5777	www.omadaw orldwide.com	Contract Carrier	None

Name	Address	Phone	Website	Туре	Penalty Record (5 years)
Online Transport, Inc.	6311 W Stoner Dr, Greenfield, IN 46140	(317) 894- 2159	http://www.onli netransport.co m/	Contract Carrier	None
Ross Transportation Services, Inc.	36790 Giles Road, Grafton, OH 44044	(440) 366- 2000	http://www.ros senvironmenta l.com/services /transportation /	Hazardous Waste Transporter	None
Sodrel Logistics, LLC	1 Sodrel Dr, Clarksville, IN 47129	(812) 282- 7941	http://www.sod reltrucklines.c om	Contract Carrier	None
Stericycle, Inc.	2355 Waukegan Rd, Bannockburn, IL 60015	(847) 367- 5910	www.Stericycl e.com	Hazardous Waste Transporter	None
Tri-State Motor Transit Co.	8141 E 7th St, Joplin, MO 64801	(877) 860- 1600	https://tristates ecured.com/	Contract Carrier	None
United Parcel Service, Inc.	55 Glenlake Parkway NE, Atlanta, GA 30328	(800) PICK- UPS	www.UPS.co m/	Carrier	Closed Case 9/18/201 9 VA- 2019- 0057- US1436"
United States Postal Service	475 L'Enfant Plaza SW, Washington, DC 20260	(202) 268- 2000	www.USPS.co m/	Carrier	See USPS SEC filings
Waste Recovery Solutions, LLC	343 King St, Myerstown, PA 17067	(336) 683- 0809	<u>www.covanta.</u> <u>com</u>	Hazardous Waste Transporter	None

# D. Disposal Facilities

Name	Address	Phone	Website	Туре	Penalty Record (5 years)
Clean Harbors Aragonite, LLC	11600 North Aptus Rd, Grantsville, UT 84029	(435) 884- 8900	www.clea nharbors.c om	Hazardous Waste Incinerator	See Appendix E
Curtis Bay Energy, LP	3200 Hawkins Point Road, Baltimore, MD 21226	(855) 228- 1715	www.curti sbayenerg y.com	Medical Waste Incinerator	See Appendix E
Heritage Thermal Services – Ohio	1250 Saint George Street, East Liverpool, OH 43920	(800) 545- 7655	<u>http://www</u> <u>.heritage-</u> <u>thermal.co</u> <u>m/</u>	Hazardous Waste Incinerator	See Appendix E
Ross Incineration Services, Inc.	36790 Giles Road, Grafton, OH 44044	(440)-748- 5800	http://www .rossenvir onmental. com/	Hazardous Waste Incinerator	See Appendix E
Stericycle, Inc., Warren, Ohio Facility	1901 Pine Avenue S.E., Warren, OH 44483	(330) 393- 0370	https://ww w.stericycl e.com/ser vice- locations/ ohio/warre <u>n</u>	Medical Waste Incinerator	None

# XI. Unwanted Medicine Educational and Outreach Programming

### **Overview**

Per Ordinance § 4.116.060, the following communications plan includes a description of the public education and outreach efforts that MED-Project will undertake to educate Residents about the collection and disposal of Unwanted Medicine from households.

### A. Audiences

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

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

The Program includes efforts to reach the Residents that are 18 years of age and older; outreach to community organizations serving a broad range of audiences; provide the Call Center in the Required Languages; and provide educational information through a range of media platforms.

#### **B.** 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 medicine 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 medicine;
- 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).

### C. Tools/Communications Channels

The education and outreach program will include multiple and varied elements designed to reach Residents and provide consistent access to timely and relevant information. MED-Project will employ paid media best practices that aid in message association and program awareness.

MED-Project provides information about how to obtain printed materials on an annual basis during site visits to Kiosk Drop-Off Sites, and upon request, to LEAs, pharmacies, health care providers and systems, health associations, local government agencies, veterinarians, veterinary hospitals, and other community organizations.

MED-Project's communication tools and channels will include the following.

#### 1. Phone

MED-Project provides 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 24 hours a day, seven days a week. The Call Center provides:

- Human representatives are available in English and Spanish. If a caller requires assistance in another language, human representatives are available to provide additional assistance through a translation service with live translation in the Required Languages. 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 Package 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
- TTY services for Residents who are speech and hearing impaired.

Please see Appendix F for a sample diagram of the Call Center flow.

#### 2. MED-Project Website

MED-Project has a mobile-friendly MED-Project Website with translations in the Required Languages. The MED-Project Website provides web 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. The Plan includes sample web pages for the MED- Project Website. See Appendix G. The MED-Project Website includes access contact information for Residents and a frequently asked questions ("FAQ") section. Translations of the FAQ are available in the Required Languages.

Community and government organizations and other public interest groups seeking materials to promote the Program are encouraged to access these resources.

The MED-Project Website is:

- Mobile-responsive and accessible by common device and browser systems.
- Translated into multiple languages using a commercially available third-party translate-based product, including in the Required Languages.
- Maintained to keep information up-to-date and accurate.

The MED-Project Website content provides:

- Information on collection options for Unwanted Medicine.
- A list of Kiosk Drop-Off Sites, including a ZIP code-based map locator provided on a publicly available, third-party platform to help Residents find the nearest disposal locations.
- A mechanism to accept requests for Mail-Back Packages from Residents.
- Information to promote the Program, including instructions for safe handling and proper disposal of Unwanted Medicine.
- User-friendly access to public service announcements used in MED-Project's media campaigns.
- Links to MED-Project's social media webpages.

#### 3. Materials

Educational materials about the Program and how to properly dispose of Unwanted Medicine are available on the MED-Project Website and are provided to the Kiosk Drop-Off Sites, potential third-party partners and community organizations, upon request.

To avoid wastage, MED-Project will provide information annually on how to request educational and promotional materials to pharmacies, health care facilities, veterinary facilities, and other interested parties for dissemination to Residents. This allows these facilities and other interested parties to request and provide input on the quantity of desired materials which, in MED-Project's experience, prevents wastage associated with sending unsolicited or undesired materials.

MED-Project will annually contact pharmacies, health care facilities, and veterinary facilities in the County to offer printed outreach materials. MED-Project utilizes the California Department of Consumer Affairs website at <a href="https://www.dca.ca.gov/consumers/public\_info/index.shtml">https://www.dca.ca.gov/consumers/public\_info/index.shtml</a> to identify new facilities to contact annually to offer printed outreach materials.

MED-Project will encourage participating locations to display outreach materials in high traffic areas. Accordingly, MED-Project will continue to provide materials, as requested, to facilities and will encourage that these materials be prominently displayed.

Educational materials will be reviewed at least every two years and will be updated as needed based on the review. These materials will use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency and will be provided in Required Languages.

#### 4. Media Outreach

The education and outreach program will include multiple and varied elements designed to reach Residents and provide consistent access to timely and relevant information. MED-Project will employ paid media best practices that aid in message association, and program awareness.

MED-Project shall rely on efficient, broad reach, digital tactics to deliver the bulk of advertising impressions and provide consistent messaging during each reporting year. These digital tactics may be supplemented by offline channels, where needed, to further bolster reach among Residents. The final media mix and channel allocation will be based on a detailed media planning process and may be subject to change.

# XII. Survey

Per Ordinance § 4.116.060(a)(4), MED-Project coordinates with all 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. See Coordination Section XIX.

Survey questions are 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 are submitted to the Director for review and comment at least thirty (30) days prior to distribution. Results of the survey are reported to the Director and made public on the MED-Project Website described under Section XI.D. The privacy of all survey respondents is maintained.

The biennial survey is 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
- 3. 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.

The following section describes the policies and procedures maintained for the Program relating to training and meeting applicable laws, regulations, and legal requirements. The relevant policies and procedures are codified in or required under MED-Project's agreements with its Vendors, Kiosk Drop-Off Site Hosts, LEAs, and LEAs supporting Take-Back Events involved in the collection and disposal of Unwanted Medicine under the Program.

MED-Project will, at least annually, verify via inspection, that all Kiosk Drop-Off Site Hosts are compliant with applicable federal and state laws, rules, and regulations as contractually required for their participation in the Program.

MED-Project will verify collection and disposal Vendor performance via periodic Vendor audits and annually through:

- Review of Vendor documentation.
- Review of processes and procedures for compliance with relevant regulatory agency requirements.
- Review of processes and procedures to ensure satisfactory service levels are in place to ensure the secure collection and disposal of covered drugs.

MED-Project contracts for Vendors involved in the collection and disposal of Unwanted Medicine collected under the Program require that Vendor:

- Follow all applicable laws, regulations, and other legal requirements.
- Maintain all professional and governmental permits, licenses, consents, authorizations, and certifications required by applicable laws for the performance of Program services.
- Provide certification that all applicable employee trainings are complete.
- Comply with industry-standard safety and security procedures.
- Use commercially reasonable measures to prevent theft or diversion of covered drugs.
- Report safety, security, or other procedural deviations.
- Maintain comprehensive information security programs and notify MED-Project in the event of a data breach.

MED-Project agreements with Kiosk Drop-Off Site Hosts require that the Kiosk Drop-Off Site:

- Comply with all applicable laws regarding the collection, handling, processing, and disposal of covered drugs.
- Possess all required authorizations to enter into an agreement for Program services.
- Identify a responsible manager and provide qualified staff.
- Complete documentation under all applicable laws for kiosk delivery, installation, or removal and for covered drug collection, storage, transportation, or disposal.
- Establish and implement procedures limiting access to kiosk keys to qualified staff.

MED-Project agreements for Take-Back Events require that law enforcement:

- Maintain compliance with all applicable laws regarding the collection, handling, processing, and disposal of Unwanted Medicine.
- Possess all required authorization to enter into an agreement for Program services.

## 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) ; 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 noncontrolled substances at Kiosk Drop-Off Sites and Take-Back Events, and through Standard Mail-Back Services per the DEA Rule. 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;
- 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; and
- The Program's total expenditures.

# XVI. Coordination

MED-Project will coordinate with all other approved stewardship plans to meet the requirements set forth in Ordinance § 4.116.060.

MED-Project will implement a single system of promotion that uses a variety of outreach tactics, and that involves coordination with other approved stewardship plans to offer printed materials, including posters and brochures, and a single toll-free telephone number, a single website, and a single survey. This single system of promotion will be implemented pursuant to the Terms of Coordination agreed to by MED-Project and the other approved program operator on September 7, 2023. Such Terms of Coordination are attached hereto as Appendix H.

# Appendix A

# Participating Kiosk Drop-Off Sites

Account Name	Street Address	City	Zip/Postal Code
Belmont Police Department	1 Twin Pines Lane	Belmont	94002
Brisbane Police Department	50 Park Place	Brisbane	94005
Broadmoor Police			
Department	388 88th Street	Broadmoor	94015
Chinese Hospital Outpatient Center Pharmacy	386 Gellert Boulevard, Suite A	Daly City	94015
County of San Mateo Juvenile Courthouse - Youth	222 Paul Scannell		
Services Center	Drive	San Mateo	94402
CVS Pharmacy 00550	1324 San Carlos Avenue	San Carlos	94070
CVS Pharmacy 09172	11 El Camino Real	San Carlos	94070
CVS Pharmacy 09216	60 Cabrillo Highway North	Half Moon Bay	94019
CVS Pharmacy 09329	1039 El Camino Real	Redwood City	94063
CVS Pharmacy 09554	77 Bovet Road	San Mateo	94402
CVS Pharmacy 09690	1301 Broadway	Redwood City	94063
CVS Pharmacy 09752	375 Gellert Boulevard	Daly City	94015
CVS Pharmacy 09807	10 Bayhill Shopping Center	San Bruno	94066
CVS Pharmacy 09811	1871 El Camino Real	Burlingame	94010
CVS Pharmacy 09833	4242 South El Camino Real	San Mateo	94403
CVS Pharmacy 09879	987 East Hillsdale Boulevard	Foster City	94404
CVS Pharmacy 09940	872 North Delaware Street	San Mateo	94401
CVS Pharmacy 09977	124 De Anza Boulevard	San Mateo	94402
CVS Pharmacy 10165	135 Pierce Street	Daly City	94015
CVS Pharmacy 10240	700 El Camino Real	Menlo Park	94025
Daly City Police Department	333 90th Street	Daly City	94015
Drew Center Pharmacy	2242 University Avenue	East Palo Alto	94303
East Palo Alto Police Department	141 Demeter Street	East Palo Alto	94303
Half Moon Bay Pharmacy	40 Stone Pine Road, Suite I	Half Moon Bay	94019

Account Name	Street Address	City	Zip/Postal Code
Hillsborough Police	1600 Floribunda		
Department	Avenue	Hillsborough	94010
Kaiser Daly City 1FI OP	395 Hickey		
Pharmacy 341	Boulevard 1st Fl	Daly City	94015
Kaiser Redwood City Marshall MOB OP Pharmacy 370	905 Maple Street, Floor 1, Room 1250	Redwood City	94063
Kaiser Redwood Cypress MOB Pharmacy 371	1150 Veterans Blvd	Redwood City	94063
Kaiser S SF Main Pharmacy 351	1200 El Camino Real	South San Francisco	94080
Kaiser San Bruno Bayhill			
Pharmacy 353	801 Traeger Avenue	San Bruno	94066
Kaiser San Bruno OP 357	901 El Camino Real	San Bruno	94066
Kaiser San Mateo MOB Pharmacy 339	1000 Franklin Parkway Fl1	San Mateo	94403
Menlo Park Police Department	701 Laurel Street	Menlo Park	94025
North East Medical Services	211 Eastmoor		
(NEMS)Eastmoor Pharmacy	Avenue	Daly City	94015
Pacifica Police Department	2075 California 1	Pacifica	94044
Redwood City Police			
Department	1301 Maple Street	Redwood City	94063
Rite Aid 05885	170 San Mateo Road	Half Moon Bay	94019
Rite Aid 05890	1400 Linda Mar Shopping Center	Pacifica	94044
Rite Aid 05891	200 Fairmont Shopping Center	Pacifica	94044
Rite Aid 05892	340 Woodside Plaza	Redwood City	94061
Rite Aid 05893	2150 Roosevelt Avenue	Redwood City	94061
San Bruno Police Department	1177 Huntington Avenue East	San Bruno	94066
San Mateo County Health - San Mateo Medical Center	222 West 39th Avenue, Room 121	San Mateo	94403
San Mateo County Sheriff's Office	400 County Center, 3rd Floor	Redwood City	94063
San Mateo County Sheriff's Office - Coastside Patrol Bureau	500 California Avenue	Moss Beach	94038

Account Name	Street Address	City	Zip/Postal Code
San Mateo County Sheriff's			
Office - Half Moon Bay			
Sheriff's Office Substation	537 Kelly Avenue	Half Moon Bay	94019
San Mateo County Sheriff's			
Office - Millbrae Police			
Bureau	581 Magnolia Avenue	Millbrae	94030
San Mateo County Sheriff's			
Office - San Carlos Patrol			
Bureau	600 Elm Street	San Carlos	94070
San Mateo Police			
Department	200 Franklin Parkway	San Mateo	94403
South San Francisco Police		South San	
Department	1 Chestnut Avenue	Francisco	94080
		South San	
Sunshine Center Pharmacy	1166 Mission Road	Francisco	94080

## **Mail-Back Distribution Location**

Account Name	Street Address	City	Zip/Postal Code
Hometown Healthcare	3 Portola Road	Portola Valley	94028

# Appendix B Sample Kiosk and Signage



## Sample Kiosk Signage

Front Panel Kiosk Art

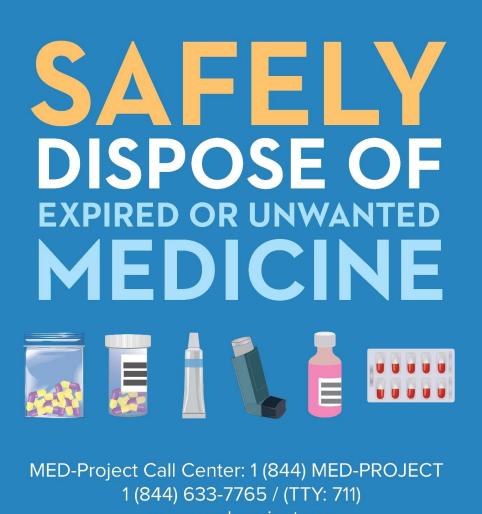


▲ PROP 65 WARNING: Entering this area, or coming into contact with items or materials in this klosk, can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.p65Warnings.ca.gov.

For more information about the MED-Project program, please to go to www.med-project.org or call 1-844-MED-PROJECT / 1 (844) 633-7765 (TTY: 711) MED-Project<sup>™</sup> Medication Education & Disposal

## Sample Kiosk Signage

Side Panel Kiosk Art



www.med-project.org



## Sample Kiosk Signage

**Drop-Slot Kiosk Art** 



# Name: 123 Pharmacy

# Contact: (555) 555-5555

USA KA 01000011ALL01.0145.02.00

# Appendix C April 16, 2019, Plan Approval



Heather Forshey, MS, REHS Director

Environmental Health Services San Mateo County Health 2000 Alameda de las Pulgas Suite 100 San Mateo, CA 94403 smchealth.org

January 16, 2020

Dr. Victoria Travis, PharmD, MS, MBA Nation Program Director, MED-Project, LLC 1800 M Street, NW Suite 400S Washington, DC 20036

RE: Notice of Determination for San Mateo County MED-Project Stewardship Plan

This letter is to provide notice that the San Mateo County MED-Project Stewardship Plan submitted on April 15, 2019 is approved by San Mateo County Environmental Health Services (EHS) as of January 1, 2020.

The Safe Medicine Disposal Ordinance 04736, (Section 4.116.030 (e) 4) states MED-Project shall start implementation of the new Plan by no later than March 31, 2020, three months after the Plan's approval date.

Please contact Waymond Wong at (650) 372-6248 with any questions or concerns.

Sincerely,

Heather Forshey, MS, REHS Director, Environmental Health Services San Mateo County



# Appendix D

Sample Standard Mail-Back Package



### **Description:**

Standard Mail-Back Package including plastic envelope with return label and instructional flyer, and unique identifier enabling tracking at collection and disposal.

### Package Size:

Standard Mail-Back Package dimensions: 8.25" x 12"

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

## Sample Injector Mail-Back Package



### **Description:**

Injector Mail-Back Packages include an FDA-cleared sharps container with mail-back packaging, return label, instructional flyer, and unique identifier enabling tracking from collection through final disposal.

### Package Size:

1.4-quart mail-back system

Injector Mail-Back Services are an example of complete, turnkey systems to provide for the safe return of Pre-filled Injector Products via USPS.

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

## Sample Inhaler Mail-Back Package



### **Description:**

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

### Package Size:

Inhaler Mail-Back Package dimensions: 9" X 7"

Inhaler Mail-Back Services 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.

# Appendix E

# **Clean Harbors Aragonite, LLC Penalty Record**

YEAR(S)	AGENCY/AREA	NOVs ISSUED	FINES PAID
2021	USEPA	Related to 2018-2019 Inspections	Resolved by consent Order - \$224, 903 fine and agreement to purchase and use FID monitors, perform quarterly monitoring, institute an improvement and replacement program, and increase internal and external audits (\$420,000 total compliance action cost)
2021	Utah Department of Environmental Quality Division of Waste Management and Radiation Control	NOV Issued in for 12 identified violations in 2020	\$21,403 fine and agreed to a Supplemental Environmental Project
2021	Utah Department of Environmental Quality Division of Waste Management and Radiation Control	NOV issued for 2019 inspection. Violations included (but not limited to) failure to: follow procedures, provide required timely notifications, properly train personnel, maintain equipment, comply with waste manifest requirements, and properly store, label, track and manage certain waste.	Resolved by Consent Order -\$80,630.
2019	US Drug Enforcement Administration (DEA)	Failure to file the ARCOS Year End Inventory. Delinquent filing of quarterly ARCOS reports for the 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> , and 4 <sup>th</sup> quarters in 2017 and for the 2 <sup>nd</sup> quarter in 2018. Failure to maintain	Resolved by Consent Order - \$96,000.

YEAR(S)	AGENCY/AREA	NOVs ISSUED	FINES PAID
		separately a biennial inventory of controlled substances. Failure to record beginning of business/close of business on the biennial inventory.	
2019	Utah Department of Environmental Quality Division of Waste Management and Radiation Control	Consent Order covered violations assessed during FY2014, FY2015, FY2016, FY2017, and FY2018 inspections including (but not limited to) failure to: follow procedures, document and report manifest discrepancies, properly maintain equipment and facility, track waste, properly categorize waste, manage infectious waste, submit timely reports, properly store waste, and maintain certain permits.	March 8, 2019 Stipulation and Consent Order - \$330,000. Fine paid in May 2021.
2018	Utah Department of Environmental Quality Division of Air Quality	Twelve violations related to timely reporting and administrative steps under Title V, NESHAP or RCRA between 2016 and 2017	Civil penalty- \$23,750

# Curtis Bay Energy, LP Penalty Record

YEAR	NOVs	FINES
2022	None	N/A
2021	None	N/A
2020	None	N/A
2019	None	N/A
2018	MDE issued a notice of violation to the facility as a result of exceeding the mercury emission limit during a stack test conducted on Incinerator EU-1 on March 21 and 22, 2018 and during a retest on May 7 and 8, 2018.	None

## Heritage Thermal Service-Ohio Penalty Record

#### Facility Summary



HERITAGE THERMAL SERVICES

1250 ST. GEORGE STREET, EAST LIVERPOOL, OH 43920 🛈 🔲 Enforcement Case Report FRS ID: 110027242320 EPA Region: 05 Latitude: 40.631622 Longitude: -80.54632 Locational Data Source: EIS Industries: Waste Management and Remediation Services Indian Country: N

### Related Reports

- Air Pollutant Report
- CWA Pollutant Loading Report
- CWA Effluent Charts
- EPA Facility Documents
- X CWA Effluent Limit Exceedances Report

View Envirofacts Reports

Enforcement and Compliance Summary

Statute	Compliance Monitoring Activities (5 years)	Date of Last Compliance Monitoring Activity	Compliance Status	Qtrs with <u>NC</u> (of 12)	Qtrs with Significant Violation	Informal Enforcement Actions (5 years)	Formal Enforcement Actions (5 years)	Penalties from Formal Enforcement Actions (5 years)	EPA Cases (5 years)	Penalties from EPA Cases (5 years)
САА	2 O	08/16/2021	Violation w/in 1 Year	7	0	17	1	\$288,000		-
CWA	-	03/17/2015	No Violation Identified	0	0	-	-		-	-
RCRA	8	02/08/2023	No Violation Identified	0	0	2	-			-

### **Regulatory Information**

Clean Air Act (CAA): Operating Major (OH0000000215020233)

Clean Water Act (CWA): Minor, Permit Effective (OH0107298)

Resource Conservation and Recovery Act (RCRA): Active LQG, Operating TSDF, (OHD980613541), Active VSQG, Toxic Releases (TRI): 43920VNRLL1250S (OHR000220285)

Safe Drinking Water Act (SDWA): No Information

Go To Enforcement/Compliance Details Known Data Problems

### Other Regulatory Reports

Air Emissions Inventory (EIS): 13429211

Greenhouse Gas Emissions (eGGRT): 1001897

Compliance and Emissions Data Reporting Interface (CEDRI): <u>CEDRI125535</u>, <u>CEDRI90484</u>

Statu	ıte		Source ID		Cu	irrent <u>SNC/HP</u>	Y	Curren	t As Of		Qtrs with <u>NC</u>	(of 12) 🛈		Data Las	t Refreshed		
CA	A	ОН	00000021502	0233		No		04/01	/2023		7				03/31/2023		
CW	A		OH0107298			No		12/31	/2022		0			03/31/2023			
RCR	RCRA OHD980613541			1		No		04/01	/2023		0			03/3	31/2023		
RCR	RCRA OHR000220285					No		04/01	/2023		0			03/3	31/2023		
nree-N	lear Com	pliance	History by	Quarter	<b>≜</b>									Oow	nload Data	$\square$	
itatute	Pro	ogram/Pollu	tant/Violation	Туре	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 1	
	CAA (Sourc	e ID: OH000	000021502023	3)	04/01- 06/30/20	07/01- 09/30/20	10/01- 12/31/20	01/01- 03/31/21	04/01- 06/30/21	07/01- 09/30/21	10/01- 12/31/21	01/01- 03/31/22	04/01- 06/30/22	07/01- 09/30/22	10/01- 12/31/22	01/0 03/31	
		Facility	Level Status		Violation Identified	Violation Identified	No Violation Identified	No Violation Identified	Violation Identified	Violation Identified	No Violation Identified	Violation Identified	Violation Identified	Violation Identified	No Violation Identified	No Violat Identi	
		HP	/ History														
	Violation Type	Agency	Programs	Pollutants													
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL						09/03/2021							
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021								
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/2022					
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL										09/23/2022			
	FRV	он	CAAMACT, CAANESH, CAANSPS,	FACIL					05/21/2021								

Stat	ute		Source ID			Current S	NC/HPV		Current As Of		Qtrs with <u>NC</u> (of 12)				Last Refresh	ed		
CA	A	он	00000002150	20233		N	<b>b</b>		04/01/2023			7			03/31/2023			
CW	/A		OH0107298			N	0		12/31/2022			0			03/31/2023			
RCI	RA		OHD9806135	41		N	, ,		04/01/2023		0				03/31/2023			
RCI	RA		OHR0002202	85		N	<b>.</b>		04/01/2023			0		03/31/2023				
														Download Data				
			History b															
Statute			itant/Violation		QTR 1 04/01-			R3 QTI 01- 01/0		QTR 6			QTR 9 04/01-					
	CAA (Source	E ID: 0H000	00002150202	(3)	06/30/2		N	1/20 03/3		09/30/2	12/31/2 No	1 03/31/22	06/30/2	2 09/30/2	2 12/31/2 No	2 03/31 No		
		Facility	-Level Status		Violation Identifie		tified Viola		tion Violation		n Violatio				1 Violatio	n Violat		
		HP	/ History															
	Violation Type	Agency	Programs	Pollutan	ts													
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL						09/03/20	21							
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/202	1								
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/202	12					
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL										09/23/20	22			
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/202	1								
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/202	2					
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL		09/11/	2020											
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/202	1								
CAA	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL	05/15/202	5												
саа	FRV	он	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL									06/03/20	22				
itatute	Program/Po		lation (	TR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTRs	QTR 9	QTR 10	QTR 11	QTR 12	QTR 13+		
CW	A (Source ID: C	Type (H0107298)		1/01-	04/01-	07/01-	10/01-	01/01-	04/01-	07/01-	10/01-	01/01-	04/01-	07/01-	10/01-	01/01-		
- Ch		-Level Statu	03	No	No	No Violation	12/31/20 No Violation	03/31/21 No Violation	06/30/21 No Violation	09/30/21 No Violation	12/31/21 No Violation	03/31/22 No Violation	06/30/22 No Violation	09/30/22 No Violation	12/31/22 No Violation	03/31/2 Undetermi		

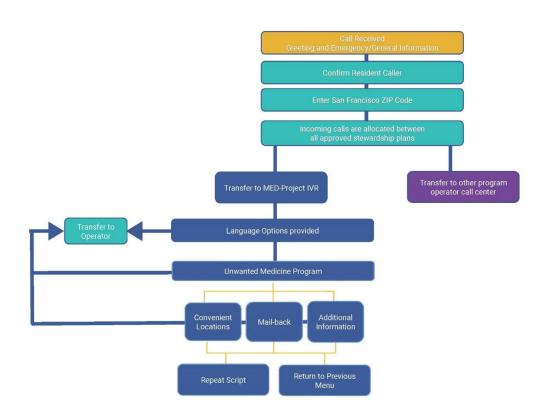
Statute	Program	/Pollutant/Violat Type	ion QTR 1	QTR 2	QTR 3		QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	Q	'R 12+	
RCRA	(Source ID:	OHD980613541)	04/01- 06/30/20	07/01- 09/30/20	10/01- 12/31/2		1/01- 2/31/21	04/01- 06/30/21	07/01- 09/30/21	10/01- 12/31/21	01/01- 03/31/22	04/01- 06/30/22	07/01- 09/30/22	10/01- 12/31/2		1/01-  31/23	
	Facil	ity-Level Status	No Violation Identified	No Violation Identified	No Violat Identifie		Violation	lo Violation Identified	No Violation Identified	No Violation Identified	No Violation	No Violation Identified	No Violation Identified	No Violati Identifie		iolation	
	Violatio	on Agend															
RCRA	A (Source ID:	OHR000220285)	04/01- 06/30/20	07/01- 09/30/20	10/01- 12/31/2		1/01- 1/31/21	04/01- 06/30/21	07/01- 09/30/21	10/01- 12/31/21	01/01- 03/31/22	04/01- 06/30/22	07/01- 09/30/22	10/01- 12/31/2		1/01-  31/23	
	Facil	ity-Level Status	No Violation Identified	No Violation Identified	No Violat Identifie		Violation N entified	lo Violation Identified	No Violati Identifie		iolation ntified						
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St	tatute	Sy	rstem		Source I	D			Type of A	Action		Lead Age	ncy		Date		
(	CAA	IC	IS-Air	оно	000000215	020233			Notice of V	liolation		State		0	9/02/2022		
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(	CAA	IC	IS-Air	оно	000000215	020233			Notice of V	liolation		State		0	2/22/2022		
(	CAA	IC	IS-Air	ОНС	000000215	020233			Notice of V	lolation		State		1	1/08/2021		
(	CAA	IC	IS-Air	оно	000000215	020233			Notice of V	lolation		State		0	8/27/2021		
(	CAA	IC	IS-Air	оно	000000215	020233		Notice of Violation				State			05/12/2021		
(	CAA	IC	IS-Air	OH000000215020233					Notice of Violation			State		02/17/2021			
(	CAA	IC	IS-Air	OH000000215020233					Notice of Violation			State		11/24/2020			
(	CAA	IC	IS-Air	OH000000215020233					Notice of Violation			State		0	9/04/2020		
(	CAA	IC	IS-Air	OH000000215020233					Notice of Violation			State		0	05/11/2020		
0	CAA	IC	IS-Air	OH000000215020233					Notice of Violation			State	02/24/2020				
	CAA		ICIS-Air	c	H0000000	15020233			Notice of	fViolation		Stat	A		11/20/2019		
	CAA		ICIS-Air		0000000			Notice of Violation							08/27/2019		
	CAA		ICIS-Air	-	00000002			Notice of Violation				State			05/17/2019		
	CAA		ICIS-Air		0000000			Notice of Violation				Stat			02/27/2019		
	CAA		ICIS-Air		H0000000				Notice of Violation				e		08/10/2018		
	CAA		ICIS-Air	c	00000002	215020233			Notice of	fViolation		Stat	e		05/30/2018		
	RCRA		RCRAInfo		OHD980	513541			WRITTEN	INFORMAL		Stat	e		09/19/2019		
	RCRA		RCRAInfo		OHD980	513541		WRITTEN INFORMAL EP/							11/02/2018		
			s "informal enforcen	•								Federal	State/Local	Penalty		Com	
atute	System	Law/Section	Source ID	Type of Action		Lead Agency	Case Name	Issued/Filed Date	d Settlemer	nts/Actions	Settlement/Action Date	Penalty Assessed	Penalty Assessed	Amount Collected	SEP Value	Actio	
CAA	ICIS-Air	112	AIR/OH000000215	020233 Judicia	2015-	EPA	HERITAGE -WTI	10/18/2018		1	04/01/2022	\$288,000	\$0	\$288,000	\$302,500	\$305,0	

# **Ross Incineration Services, Inc. Penalty Record**

YEAR	AGENCY	NOVs ISSUED	FINES PAID
2022	U.S. EPA	Finding of Violation proposed in	Consent Agreement and
2022	0.3. LFA	2020 regarding breakthrough on tank interfaces under the Benzene	Final Order requiring third party evaluation of Leak
		national Emission Standards for Hazardous Air Pollutants	Detection and Repair programs and payment of
		regulations.	\$95,000 fine.
2021	U.S. EPA	Notice of Potential Violation and Opportunity to Confer issued in 2020 regarding use of a barge to store waste without a permit.	Consent Agreement and Final Order provided permission to continue to use barge to repackage waste and payment of \$20,015 fine.
2020	OEPA	NOV issued in response to voluntary disclosure of discharge of combustion gasses containing carbon monoxide in excess of RIS hourly rolling average.	None. Considered resolved by OEPA.
2019	OEPA	NOV issued in response to 10/23/2019 voluntary disclosure of noncompliance with waste storage time limits.	RIS received letter indicating return to compliance 12/17/2019.
2019	OEPA	Two container management violations issued during 9/9/2019 - 9/11/2019 inspection	None, Violations were abated at time of inspection.
2019	OEPA	Three container management violations issued during 6/18/2019 inspection	None, violations abated at time of inspection.
2018	OEPA	NOV issued in response to 8/27/2018 voluntary disclosure of noncompliance with waste storage time limits	Civil Penalty of \$20,000.
2018	OEPA	Two facility generated waste containers were open during 6/25/2018 inspection.	Both containers closed during inspection and violation was resolved.
2018	OEPA	NOV issued 5/30/2018 in response to violations reported in 2018 quarterly deviation report.	None. Considered resolved by OEPA.
2018	OEPA	One container management violation issued during 3/12/2018 – 3/14/2018 inspection	None, violations abated at time of inspection.

# Appendix F Sample Call Center Flow

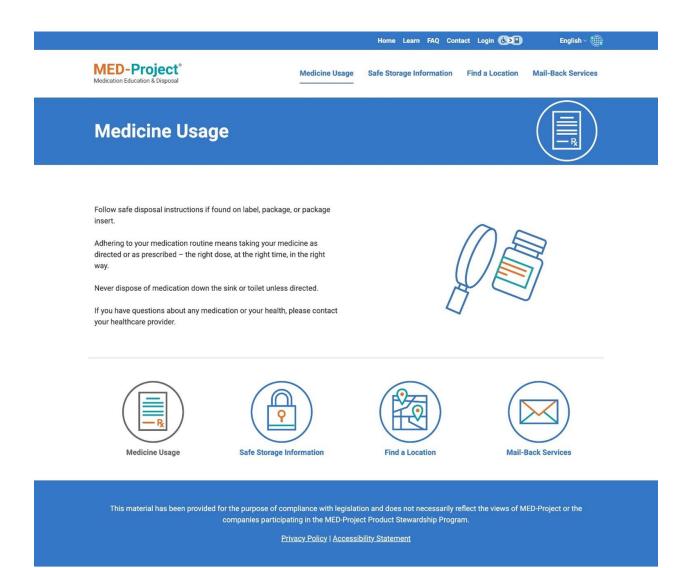
Thank you for calling the information line for the Medication Education and Disposal Project, or MED-Project.



# **Appendix G**

## Sample MED-Project Website Pages

Home Learn FAQ Contact Login 🔥 🗐 English - 🌰 MED-Project® Medication Education & Disposal Medicine Usage Safe Storage Information Find a Location Mail-Back Services San Mateo County, CA -Medicine Disposal Program MED-Project provides collection and disposal of unwanted or expired medicine at convenient locations in your area or via mailback package. Proper disposal is safe and easy. **Get Started** What should you do with your expired or unwanted medicines? Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It is important that patients take their medicines as prescribed by their health care provider. 6 However, if you have expired or unwanted medicines, proper disposal is important and easy. Learn more about the program 9 Medicine Usage Safe Storage Information Find a Location Mail-Back Services in This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of MED-Project or the companies participating in the MED-Project Product Stewardship Program. Privacy Policy | Accessibility Statement





It is important to take medication as prescribed by your health care provider and as indicated on the label or packaging. Always be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children. If you have expired or unwanted household medication, proper storage and disposal are easy. To protect your family, pets, and community, follow these instructions for secure storage and safe disposal:

#### **Use as Directed**

Use medication as directed. If there are any specific instructions on the label, package, or package insert, please follow those. If you have any questions, ask your healthcare providers.

#### **Store Securely**

Follow storage instructions as provided on medicine labels and on the information accompanying medicine. Keep medication in a secure location safely away from people or pets that might come in contact with them.

#### **Dispose Safely**

Check your medicine cabinet and remove all expired and unwanted medication. If you do not know if a drug is still safe, check with your pharmacist. Count medication to keep track of amounts. Drop off or mail back expired or unwanted medications for safe disposal.

Please separate and remove any items and medication that are not accepted before disposing. Do not place medicine in the trash or recycling and never flush them down the sink or toilet.

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







Safe Storage Information





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#### **Convenient Locations**

Community kiosk drop-off sites allow residents to bring expired or unwanted medicine to convenient locations for proper disposal.

Your Coverage Area

Enter your zip code to find a o	onvenient location near you.
Starting Point	Radius

Zip Code	D	5 Miles	Search
O Zip Code 🔿 Address	_		

### Filter Results

Select All
Medicine Kiosks



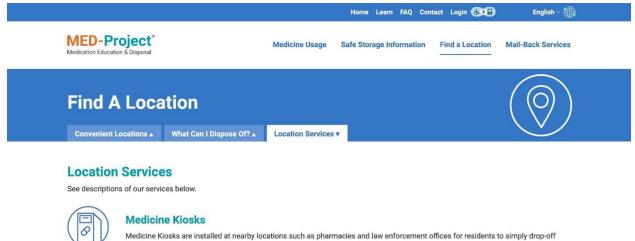
#### Location Information

Menio Park Police Dep	artment	Daly City Police Depart	ment
701 Laurel Street		333 90th Street	
Menio Park, CA, 94025		Daly City, CA, 94015	
Get Directions		Get Directions	
(650) 330-6300		(650) 991-8119	
Services Provided ①	Hours of Operation	Services Provided (1)	Hours of Operation
Medicine Kiosks	Monday 7:30 AM - 5:30 PM	Medicine Klosks	Monday 8:00 AM - 6:00 PM
	Tuesday 7:30 AM - 5:30 PM		Tuesday 8:00 AM - 6:00 PM
	Wednesday 7:30 AM - 5:30 PM		Wednesday 8:00 AM - 6:00 PM
	Thursday 7:30 AM - 5:30 PM		Thursday 8:00 AM - 6:00 PM
	Friday 8:00 AM - 5:00 PM		Friday 8:00 AM - 6:00 PM
			Saturday 8:00 AM - 12:00 PM



MED-Project LLC has compiled this list based on publicly available information for your convenience, but does not guarantee the accuracy of any of the information on it. MED-Project LLC does not endorse and denies any responsibility or liability for the programs listed or the processes they employ for collection, transportation, treatment, or disposal of the medications they collect.





Medicine Kiosks are installed at nearby locations such as pharmacies and law enforcement offices for residents to simply drop-off their expired or unwanted medicine for safe and free disposal.

Note: not all services are available at each location. Visit the Find a Location page to find out what services are available at a specific collection site.



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MED-Project* Medication Education & Disposal	Medicine Usage			
Medication Education & Disposal		Safe Storage Information	Find a Location	Mail-Back Services
Convenient Locations A What Can I Dispose O	0f? ▼ Location Services ▲			$\bigcirc$

### What Can I Dispose Of?

Below are general guidelines for the products that will and will not be accepted in kiosks.

### Medicine

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

Medical devices

Mercury-containing thermometers

Batteries

Sharps

Illicit drugs

#### Accepted

Medication in any dosage form, except for those listed below, in their original container or sealed bag are accepted.

### **Not Accepted**

- Herbal remedies
- Vitamins
- Supplements
- Cosmetics
- Other personal care products
- If transferring medications to a sealed bag, please be sure to recycle remaining packaging.

Do not place medicine in the trash or recycling, and never flush them down the toilet.

For more information about the County of San Mateo Safe Medicine Disposal Ordinance, please see: www.smchealth.org/rxdisposal

For more information about the sharps disposal information in the County of San Mateo, please see: www.smchealth.org/sharps



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		Home Lear	n FAQ	Contact	Login 🚱	English - 👾	
MED-Project <sup>6</sup> Medication Education & Disposal	Medicine Usage	Safe Storage I	nformatio	on Fi	nd a Location	Mail-Back Services	
Mail-Back Services							

MED-Project provides the following different types of Mail-Back Packages at no charge to residents. Please complete the below form to request a pre-paid, pre-addressed mail-back package. Instructions for disposal will be provided with all mail-back services. Please submit separate forms for each type of mail-back package.

will be provided with all mail-back services. Please submit separate forms for each type of mail-back package. To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

Mail-Back Services are available to disabled and/or homebound residents upon request. Home healthcare professionals providing services to disabled and/or homebound residents may also request a Mail-Back Package on their behalf.

#### Package Type and Quantity

Choose your package type*	~ Quantity	~		
Contact Information				
First Name*	D	Last Name*		R
Email				E)
Address*				Ee.
Apt #, Building #, Suite #				
City*	b	CA	Zip Code*	E)
* Required field				
Submit Request				

Please click the submit button only once to prevent accidental and multiple submissions.

### Accepted Medicine Accepted Inhalers Accepted: Medication in any dosage form, except for those identified as not accepted below, in their original container or sealed bag are accepted. Accepted: Only place undamaged inhalers in their original containers in the Inhaler Mail-Back Package. Not Accepted: Inhaler Mail-Back Packages can only be used for inhalers and cannot accept other types of items. Not Accepted: - Herbal remedies - Vitamins - Supplements - Cosmetics - Other personal care products - Medical devices Batteries Mercury-containing thermometers Sharps Illicit drugs Inhalers If transferring medications to a sealed bag, please be sure to recycle remaining packaging. Do not place medicine in the trash or recycling, and never flush them down the toilet. Accepted Injectors Accepted: Injector Mail-Back Packages can only be used for pre-filled injector products. Not Accepted: • Injector Mail-Back Packages cannot be used for inhalers or other types of unwanted medicine. - R<sub>2</sub> Æ Find a Lo Mail-Back Ser



### **Outreach and Education**

Part of MED-Project's mission is to reach out to the local community and educate residents about proper disposal of household unwanted medicine and sharps.

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

There are a number of ways to dispose of expired or unwanted medicines. To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicines.

For additional information on the program, MED-Project has developed an educational toolkit which includes the materials below.



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



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### **Outreach and Education**

Part of MED-Project's mission is to reach out to the local community and educate residents about proper disposal of household unwanted medicine and sharps.

### Safely Dispose of Expired or Unwanted Medicine

#### What Should You Do With Your Expired or Unwanted Medicine?

There are a number of ways to dispose of expired or unwanted medicine. Medicine helps treat diseases, manages chronic conditions, and improves health and well-being for millions of Americans. It is important that patients take their medicine as prescribed by their health care provider, and as indicated on the label or packaging. It is also important to be sure to store medicine securely to prevent accidental ingestion or misuse by others, especially children. If you have expired or unwanted medicine, proper disposal is easy.

If you have expired or unwanted medicine, proper disposal is easy. To protect your privacy, patients are reminded to remove all personally identifiable information on medication labels or packaging before disposing of unwanted medicine.

#### What items can I dispose of at a kiosk?

Accepted: Medication in any dosage form except for those listed as Not Accepted below, in their original container or sealed bag.

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

Not Accepted: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, medical devices, batteries, mercury-containing thermometers, sharps, and illicit drugs.

#### **Disposal of Household Medicine**

#### Check the Package

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

#### **Convenient Locations**

To find kiosk 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.

#### Mail-Back

Mail-Back Services for unwanted medicine, pre-filled injector products, and inhalers are available. Visit the Mail-Back section of www.med-project.org.

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

For more information about the MED-Project program, visit www.med-project.org or call 1 (844) MED-PROJECT or 1 (844) 633-7765 (TTY: 711).



Medicine Usage



Safe Storage Information





Mail-Back Services

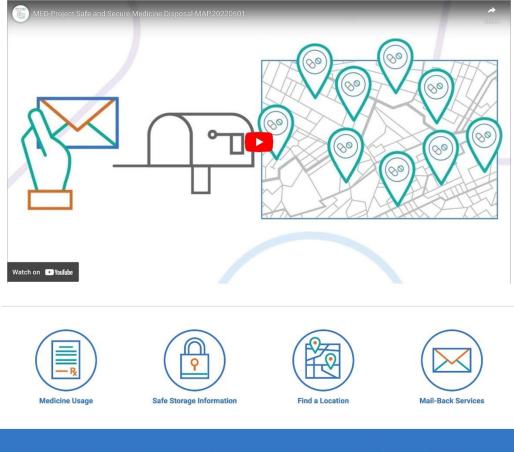
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### **Outreach and Education**

Part of MED-Project's mission is to reach out to the local community and educate residents about proper disposal of household unwanted medicine and sharps.



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#### 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)

For answers to some frequently asked questions, visit the MED-Project  $\underline{\mbox{FAQ}}$  page.

#### **Convenient Locations**

If you are a current kiosk drop-off site, or a retail pharmacy, hospital/clinic with an onsite pharmacy or a law enforcement agency interested in hosting a kiosk, please contact us:

Click here:

Login or Register for an Account Call us by Phone: 1 (833) MED-PROJECT or 1 (833) 633-7765 Fax us:

1 (866) 633-1812

Email us: Email Inquiries for Medicine Disposal: sanmateocounty@med-project.org

Address:

Dr. Victoria Travis, PharmD, MS, MBA National Program Director MED-Project LLC

#### Convenient Locations/Host Sites -Request Materials

Login to your account to order brochures.

#### **Drug Producers**

If you are drug producer interested in participating in the MED-Project Stewardship Plan contact:

Phone: 1 (202) 495-3131 Email: <u>compliance@med-project.org</u>

If you are experiencing a medical emergency, please dial 911. If you are experiencing a non-emergency but suspect that you or another individual 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.







Mail-Back Services

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

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				0
What is MED-Project?				
What should I do if I am having a medical er	mergency?			
What should I do if I think I have ingested so	omething poisonous?			
What should I do if my pet has ingested me	dication?			
Whom should I call with a question about m	y medication?			
Where can I find information about the safe	storage of medication?			
How do I dispose of my expired or unwante	d medicine?			
Should I remove my personal information b	efore disposing of my media	cation?		,
Where are the MED-Project disposal locatio	ns nearest me?			2
Will it cost me anything to dispose of my ex	pired or unwanted medicati	ons?		
Can I flush my medication down the toilet?				2
I am unable to go to a kiosk or attend a take	-back event. How can I disp	ose of my expired or unwa	inted medicine?	
I have a question not answered by this web	site. Is there someone I can	contact with a question at	out MED-Project?	3
Where else can I find information about the	safe disposal of expired or	unwanted medicines?		,
What is recommended for safe disposal of	expired or unwanted medici	ne in San Mateo County?		
Where can I find information about Californ	ia's Prop 65?			

Medicine Usage







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# Appendix H

## **Single System of Promotion**

### PLAN OPERATORS' (MED-PROJECT LLC AND INMAR INTELLIGENCE) AGREED-UPON PRINCIPLES FOR THE SINGLE SYSTEM OF PROMOTION IN SAN MATEO COUNTY

This statement of principles sets forth the elements of a "Single System of Promotion," as required by the Environmental Health Division of San Mateo County (the "Department"); the San Mateo County Safe Medicine Disposal Ordinance as codified in the San Mateo County Ordinance Code, Chapter 4.116, Sections 4.116.010 through 4.116.190 ("Ordinance"). This Single System of Promotion has been agreed upon by MED-Project LLC ("MED-Project ") and Inmar Intelligence, Inc. ("Inmar"), the two Stewardship Plan operators of approved Stewardship Plans ("Plan Operators") in San Mateo County. The terms "County Residents," "Director," "Mail-back Services," "Stewardship Plan," and "Unwanted Covered Drugs," as used herein, have the same meaning as in the Ordinance.

### A. Antitrust Compliance

 The following antitrust compliance statement shall be read at the beginning of all meetings between the Plan Operators and shall be included in all writings memorializing the agendas, actions, proceedings, and outcomes of such meetings:

"MED-Project and Inmar Intelligence ("Inmar") have policies of strict compliance with federal and state antitrust laws. The antitrust laws prohibit competitors – including MED-Project and Inmar – from making agreements or engaging in actions that could result in unreasonable restraint of trade. Consequently, when engaging in any discussions between them, MED-Project and Inmar must avoid discussing any of the following topics: prices, fees, rates, profit margins, or other terms or conditions of sale; allocation of markets or customers or division of territories; or refusals to deal with or boycotts of suppliers, customers, or other third parties, or topics that may lead MED-Project and Inmar to not deal with a particular supplier, customer, or third party. If any participant senses that the meeting is drifting into any of these areas, they should notify the other participants and terminate the meeting."

### B. Kiosks (San Mateo County Ordinance Code 4.116.060(a)(2))

- Plan Operators agree that their kiosks for the collection of Unwanted Covered Drugs need not be the same in design or color.
- 2. Each Plan Operator shall independently maintain one kiosk in the County-owned pharmacy(ies).

### C. Website (San Mateo County Ordinance Code 4.116.060(a)(3))

- 1. Plan Operators will select a third-party vendor to develop and host a neutral (unbranded) landing page for their approved Stewardship Plans in San Mateo County. Each Plan Operator will contract separately with the selected vendor.
- 2. The selected vendor shall be responsible for creating and implementing a neutral landing page which will provide County Residents with:
  - A map of all kiosk locations and mail-back materials distribution sites utilized by the Plan Operators in San Mateo County, which shall be updated at least quarterly unless more frequent updating is required by law.
  - ii. A directory or listing of the Plan Operators' URLs.

- 3. The Plan Operators' URLs in the directory will send County Residents to each Plan Operator's website where information about their Stewardship Plans' activities, such as the schedule and location of take-back events; services, such as ordering mail-back envelopes; and educational and outreach materials, will be available.
- Plan Operators will utilize the Uniform Resource Locator (URL) medtakebacksanmateo.org as the neutral (unbranded) landing page for their approved Stewardship Plans in San Mateo County.
- Plan Operators will direct County Residents who initially visit their organizational websites to the neutrally branded URL medtakebacksanmateo.org.
- The neutral (unbranded) landing page shall not be used for commercial purposes, such as the sale of products or services.

### D. Toll-free Telephone Number (San Mateo County Ordinance Code 4.116.060(a)(3))

- Plan Operators will direct resident callers to the neutral toll-free telephone number, 844-482-5322 or 844-4-TAKE-BACK.
- Plan Operators will select a single third-party call center vendor for services for their approved Stewardship Plans in San Mateo County. Each Plan Operator will contract separately with the selected vendor.
- The neutral toll-free telephone number will allow County Residents to select a Plan Operator through an interactive voice response system, or other method, as agreed upon by the Plan Operators.
- The neutral toll-free telephone number shall not be used for commercial purposes, such as the sale of products or services.
- Plan Operators will direct callers who initially call their own telephone numbers to the neutral toll-free telephone number.

### E. Promotion/Media (San Mateo County Ordinance Code 4.116.060(a)(3))

 Each Plan Operator shall separately satisfy San Mateo County's promotional, language, and media requirements, and each Plan Operator, independent of the other, will provide the Mail-back Services, educational and outreach materials, and other services included in each Operator's approved Stewardship Plan.

### F. Surveys (San Mateo County Ordinance Code 4.116.060(a)(4))

- Plan Operators will coordinate conducting the surveys required in the Ordinance on a biennial basis, with sampling starting in Q1 2024.
- Plan Operators shall select a third-party survey vendor to design and implement the required surveys and shall contract separately with the selected vendor.