



A Product Stewardship Plan for Unwanted Medicine from Households

San Mateo County, CA

April 14, 2023

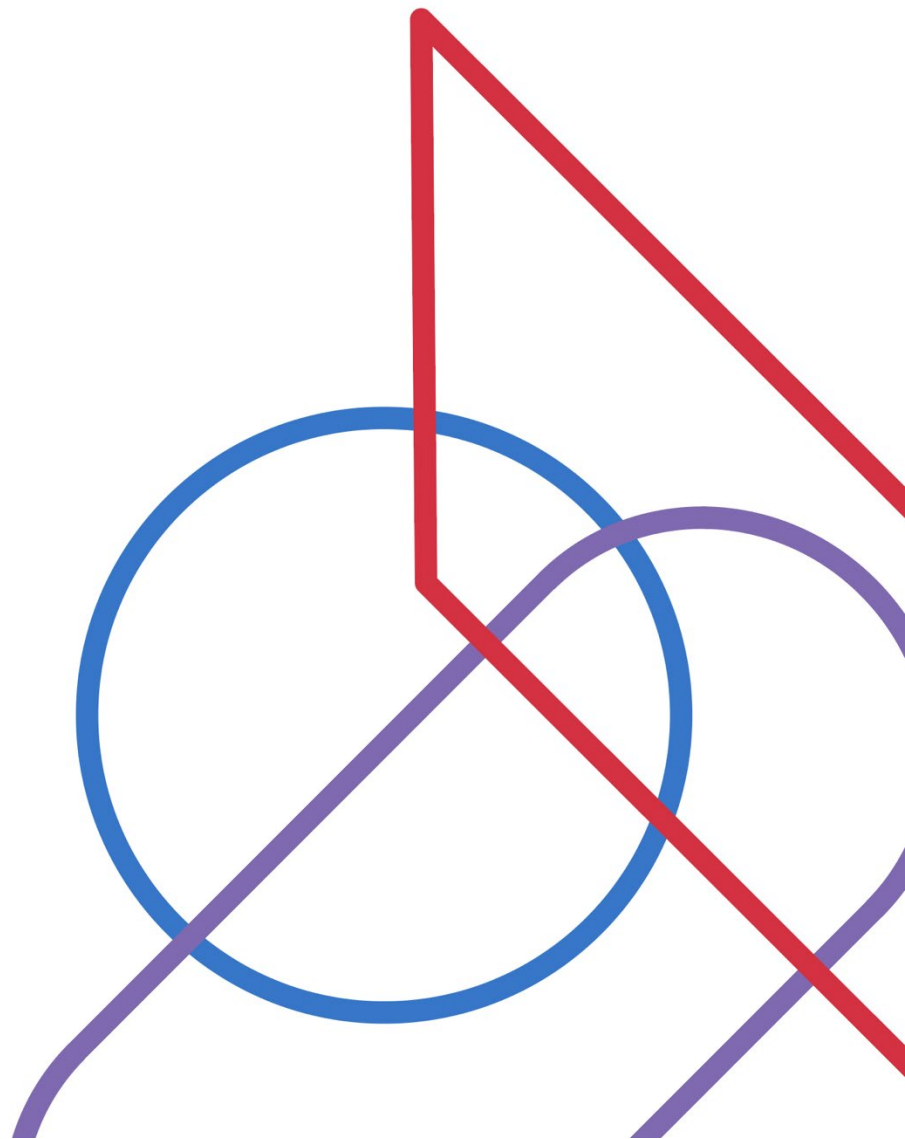


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Executive Summary

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, which has been in operation since December 2016, and has served 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 Producers¹ to develop a Product Stewardship Program to finance and manage the collection, transportation, and disposal of Unwanted Medicine from San Mateo County Residents.

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

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

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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Alora Pharmaceuticals, LLC	Avion Pharmaceuticals, LLC	1880 McFarland Parkway Suite 105	Alpharetta	Georgia	30005	United States
Alora Pharmaceuticals, LLC	Sovereign Pharmaceuticals, LLC	7590 Sand St	Ft. Worth	Texas	76118	United States
Alora Pharmaceuticals, LLC	Trigen Laboratories LLC	1880 McFarland Pkwy Ste 110	Alpharetta	Georgia	30005-1795	United States
Alora Pharmaceuticals, LLC	Vertical Pharmaceuticals, LLC	1880 McFarland Pkwy Ste 110	Alpharetta	Georgia	30005-1795	United States
Alvogen Pharma US, Inc.	Alvogen Pharma US, Inc.	44 Whippany Road	Morristown	New Jersey	07960	United States
Alvogen Pharma US, Inc.	Almaject, Inc.	44 Whippany Road	Morristown	New Jersey	07960	United States
Alvogen Pharma US, Inc.	Almatica Pharma, LLC	44 Whippany Road	Morristown	New Jersey	07960	United States
Alvogen Pharma US, Inc.	Alvogen, Inc.	44 Whippany Road	Morristown	New Jersey	07960	United States
Alvogen Pharma US, Inc.	Norwich Pharmaceuticals, Inc.	6829 State Highway 12	Norwich	New York	13815	United States
Amarin Pharma, Inc.	Amarin Pharma, Inc.	440 US Highway 22 Ste 300	Bridgewater	New Jersey	08807-2477	United States
Amerisource Health Services, LLC DBA: American Health Packaging	Amerisource Health Services, LLC DBA: American Health Packaging	2550-A John Glenn Avenue	Columbus	Ohio	43217	United States
Amgen Inc.	Amgen Inc.	One Amgen Center Drive	Thousand Oaks	California	91320	United States
Amgen Inc.	Amgen USA	One Amgen Center Drive	Thousand Oaks	California	91320	United States
Amgen Inc.	Immunex Corporation	One Amgen Center Drive	Thousand Oaks	California	91320	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Amgen Inc.	Onyx Pharmaceuticals	249 N. Grand Avenue	South San Francisco	California	94080	United States
Amneal Pharmaceuticals LLC	Amneal Pharmaceuticals LLC	400 Crossing Blvd Third Floor	Bridgewater	New Jersey	08807	United States
Amphastar Pharmaceuticals, Inc.	Amphastar Pharmaceuticals, Inc.	11570 Sixth Street	Rancho Cucamonga	California	91730	United States
Amphastar Pharmaceuticals, Inc.	International Medication Systems, LTD	1886 Santa Anita Ave	South El Monte	California	91733	United States
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
Apexia Pharmaceuticals, LLC	Apexia 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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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	Bridgewater	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	Bridgewater	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 Suite 300	Freehold	New Jersey	07728	United States
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Catalent Pharma Solutions, Inc.	Catalent CTS, LLC	10245 Hickman Mills Dr	Kansas City	Missouri	64137	United States
Catalent Pharma Solutions, Inc.	Catalent France Beenheim S.A.	74 Rue Principale	Beenheim	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
Catalent Pharma Solutions, Inc.	Catalent U.K. Swindon Zydis Limited	Frankland Road, Blagrove	Swindon, Wiltshire	N/A	SN5 8RU	United Kingdom
Chartwell RX, LLC	Chartwell RX, LLC	77 Brenner Drive	Congers	New York	10920	United States
Chiesi USA, Inc. (formerly	Chiesi USA, Inc. (formerly	175 Regency Woods Suite 600	Cary	North Carolina	27518	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Cornerstone Therapeutics, Inc.)	Cornerstone Therapeutics, Inc.)					
Church & Dwight Company, Inc.	Church & Dwight Company, Inc.	469 N Harrison St	Princeton	New Jersey	08540-3597	United States
Cintex Services, LLC	Cintex Services, LLC	5400 Laurel Springs Parkway, Suite 803A	Suwanee	Georgia	30024	United States
CitraGen Pharmaceuticals, Inc.	CitraGen Pharmaceuticals, Inc.	3789 Spinnaker Court	Fremont	California	94538	United States
Clovis Oncology, Inc.	Clovis Oncology, Inc.	5500 Flatiron Parkway	Boulder	Colorado	80301	United States
CMP Pharma, Inc	CMP Pharma, Inc	PO Box 147 8026 East Marlboro Rd.	Farmville	North Carolina	27828	United States
Colgate Oral Pharmaceuticals, Inc.	Colgate Oral Pharmaceuticals, Inc.	300 Park Avenue	New York	New York	10022	United States
Collegium Pharmaceutical, Inc.	Collegium Pharmaceutical, Inc.	100 Technology Center Drive, Suite 300	Stoughton	Massachusetts	02072	United States
Collegium Pharmaceutical, Inc.	BioDelivery Sciences, Inc.	4131 ParkLake Avenue, Suite 225	Raleigh	North Carolina	27612	United States
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 Pharmaceuticals, Inc.	Cosette Pharmaceuticals, Inc.	111 Coolidge St.	South Plainfield	New Jersey	07080	United States
Covis Pharma GmbH	Covis Pharma GmbH	Baarn, Zug Branch Grafenauweg 12	Zug	N/A	CH- 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
Curax Pharmaceuticals LLC dba Cypress, Macoven, Hawthornn	Curax 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	Waltham	Massachusetts	02451	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		3rd Floor				
Derma Care Research Labs, LLC	Derma Care Research Labs, LLC	440 Fentress Blvd	Daytona Beach	Florida	32114	United States
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	Boca Raton	Florida	33432	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Suite 760				
Eckson Labs, LLC	Eckson Labs, LLC	5400 Laurel Springs Parkway, Suite 803B	Suwanee	Georgia	30024	United States
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,	6 Ram Ridge Rd	Chestnut Ridge	New York	10977	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
	Inc. (d/b/a Par Pharmaceutical)					
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
Esperion	Esperion	3891 Ranchero Drive Suite 150	Ann Arbor	Michigan	48108	United States
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	Pittsburgh	Pennsylvania	15212	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Suite 602				
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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 Sebeth 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
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 Suite 260	Orlando	Florida	32811	United States
Insmad Incorporated	Insmad Incorporated	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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
Johnson & Johnson	Actelion	5000 Shoreline Ct STE 200	South San Francisco	California	94080	United States
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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 Pharamcal 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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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	Morgantown	West Virginia	26505	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Reg Affs				
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 Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Institutional Inc. (IL)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Institutional Inc. (TX)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Institutional LLC	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (1606-1609JP)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (20/21JP)	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 Laboratories Limited (BL)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (F4/F12OSD)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (H12/H13OSD)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (OTL)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (SF)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (SFF)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Laboratories Limited (SPD)	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Pharmaceuticals, Inc.	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Mylan Specialty L.P.	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 Technologies, Inc.	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
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
Mylan Inc.	Viartis Specialty LLC	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
Mylan Inc.	Wallace Pharmaceuticals, Inc.	3711 Collins Ferry Road Reg Affs	Morgantown	West Virginia	26505	United States
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

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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
Neurocrine Biosciences, Inc.	Neurocrine Biosciences, Inc.	12780 El Camino Real	San Diego	California	92130	United States
New World Imports	New World Imports	160 Athens Way	Nashville	Tennessee	37228	United States
Norbrook Laboratories Limited	Norbrook Laboratories Limited	Carnbane Industrial Estate	Newry, County Down	N/A	BT35 6QQ	United Kingdom
Norbrook Laboratories Limited	Norbrook, Inc.	9733 Loiret Blvd	Lenexa	Kansas	66219	United States
Nostrum Laboratories, Inc.	Nostrum Laboratories, Inc.	705 East Mulberry Street	Bryan	Ohio	43506	United States
Novartis Group Companies	Novartis Group Companies	59 Route 10	East Hanover	New Jersey	07936	United States
Novartis Group Companies	Eon Labs, Inc.	4700 Sandoz Drive	Wilson	North Carolina	27893	United States
Novartis Group Companies	Fougera Pharmaceuticals Inc.	60 Baylis Road	Melville	New York	11747	United States
Novartis Group Companies	Novartis Pharmaceuticals Corporation	1 Health Plaza	East Hanover	New Jersey	07936-1016	United States
Novartis Group Companies	Sandoz Inc.	100 College Road West	Princeton	New Jersey	08540	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

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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
Prestige Consumer Healthcare, Inc.	C.B. Fleet Company, Incorporated	660 White Plains Road,2nd Floor	Tarrytown	New York	10591	United States
Prestige Consumer Healthcare, Inc.	DenTek Oral Care, Inc.	660 White Plains Road,2nd Floor	Tarrytown	New York	10591	United States
Prestige Consumer Healthcare, Inc.	Insight Pharmaceuticals LLC	660 White Plains Road,2nd Floor	Tarrytown	New York	10591	United States
Prestige Consumer Healthcare, Inc.	Medtech Products Inc.	660 White Plains Road, 2nd Floor	Tarrytown	New York	10591	United States
Primus Pharmaceuticals, Inc.	Primus Pharmaceuticals, Inc.	7373 N Scottsdale Rd. B-200	Scottsdale	Arizona	85253	United States

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
Professional Disposables International Inc.	Professional Disposables International Inc.	400 Chestnut Ridge Rd	Woodcliff Lake	New Jersey	07677	United States
Provell Pharmaceuticals, LLC	Provell Pharmaceuticals, LLC	1801 Horseshoe Pike - Suite 1	Honey Brook	Pennsylvania	19344	United States
Puma Biotechnology	Puma Biotechnology	10880 Wilshire Boulevard Suite 2150	Los Angeles	California	90024	United States
PuraCap International, LLC	PuraCap International, LLC	517 Route 1 Suite 4002	Iselin	New Jersey	08830	United States
PuraCap International, LLC	Epic Pharma, LLC	227-15N Conduit Ave.	Laurelton	New York	11413	United States
PuraCap International, LLC	PuraCap Caribe	Carr 698 km 0.8	Bo Mameyal Dorado	Puerto Rico	00646	United States
PuraCap International, LLC	PuraCap Laboratories LLC dba Blu Pharmaceuticals	87 Glen Cove Road Unit 3A	Greenvale	New York	11548	United States
PuraCap International, LLC	PuraCap Pharmaceutical, LLC	517 Route 1 Suite 4002	Iselin	New Jersey	08830	United States
Purdue Pharma L.P.	Purdue Pharma L.P.	One Stamford Forum	Stamford	Connecticut	06901	United States
Purdue Pharma L.P.	Adlon Therapeutics, LP	One Stamford Forum	Stamford	Connecticut	06901	United States
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
SigmaPharm Laboratories LLC	SigmaPharm Laboratories LLC	3375 Progress Drive	Bensalem	Pennsylvania	19020	United States

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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
		Suite 245				
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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
Xeris Pharmaceuticals, Inc.	Xeris Pharmaceuticals, Inc.	180 N.LaSalle St	Chicago	Illinois	60601	United States
XGen Pharmaceuticals DJB, Inc.	XGen Pharmaceuticals DJB, Inc.	300 Daniel Zenker Drive	Horseheads	New York	14845	United States
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

Parent Company Name	Company Name	Street Address	City	State/Province	Zip/Postal Code	Country
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.¹

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.

¹ 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 Medicine²

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.

² 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.

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.

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 53 kiosks at 52 Kiosk Drop-Off Sites that are currently participating in the Program, identified in Appendix A, and shown in Figure 1 below.

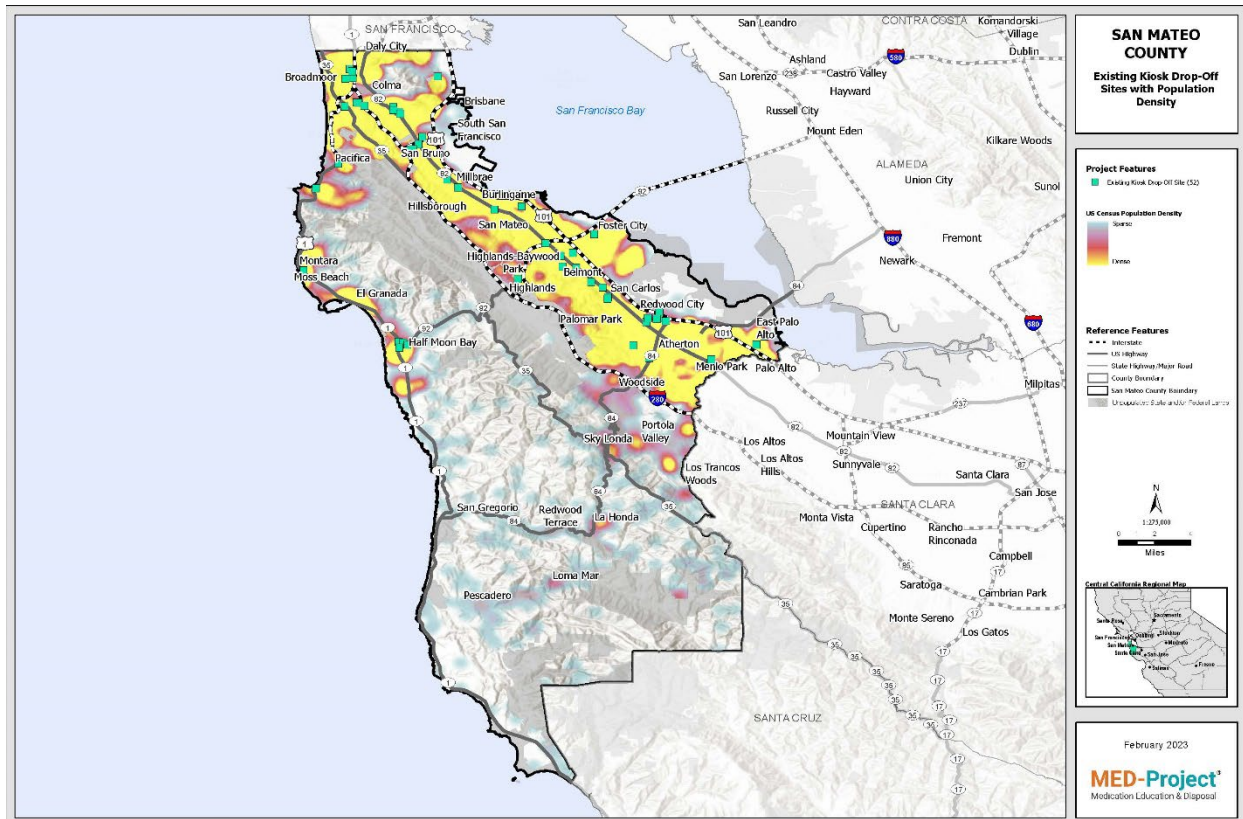


Figure 1 Existing Kiosk Drop-Off Sites

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 non-controlled substances are acceptable to be placed in the kiosk; and
- Have the small opening in the outer container locked or made inaccessible to the public when a Kiosk Drop-Off Site employee is not present.

The design of the pharmacy kiosk and signage ([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 Rule³ 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:

- 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

³ 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."

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, Vendor will typically respond to a service location within two to three business days of the event.

In addition, any items that a Resident deposit 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 is requesting approval by the Director for the use of municipal solid waste combustors for the disposal of Unwanted Medicine from the County pursuant to §§ 4.116.070(b)-(c) of the Ordinance. Please refer to MED-Project's petition included as Appendix C.

E. Mail-Back Services for 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:

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

All Mail-Back 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.
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);
- PPE Utilization;
- DEA Controlled Substance Handling Protocols;
- Health Insurance Portability and Accountability Act; ("HIPAA") Requirements; and
- OSHA Bloodborne Pathogens Standards.

X. Vendor, Transporter, and Disposal Facility Information

A. Vendors

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

B. Reverse Distributor Facilities

Name	Address	Phone	Website	Type	Penalty Record (5 years)
Covanta Environmental Solutions, LLC	2515 S. Holt Rd, Indianapolis, IN 46241	(317) 719-6397	https://www.covanta.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.com	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	Type	Penalty Record (5 years)
Clean Harbors Environmental Services Inc.	42 Longwater Drive, Norwell, MA 02061	(781) 792-5000	www.cleanharbors.com	Private Carrier	1 reported case closed 12/10/2019
Covanta Environmental Solutions Carriers II, LLC	5300 N 33rd St, Milwaukee, WI 53209	(336) 683-0809	www.covanta.com	Private Carrier	None
Covanta Environmental Solutions dba Chesapeake Waste Solutions, LLC.	190 Shellyland Road, Manheim, PA 17545	(336) 683-0809	www.covanta.com	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.heritage-enviro.com/	Hazardous Waste Transporter	None
Omada Worldwide Expedite, Inc.	853 S Columbia Road, Suite	(317) 293-5777	www.omadaworldwide.com	Contract Carrier	None

Name	Address	Phone	Website	Type	Penalty Record (5 years)
	175, Plainfield, IN 46168				
Online Transport, Inc.	6311 W Stoner Dr, Greenfield, IN 46140	(317) 894-2159	http://www.onlinetransport.com/	Contract Carrier	None
Ross Transportation Services, Inc.	36790 Giles Road, Grafton, OH 44044	(440) 366-2000	http://www.rossenvironmental.com/services/transportation/	Hazardous Waste Transporter	None
Sodrel Logistics, LLC	1 Sodrel Dr, Clarksville, IN 47129	(812) 282-7941	http://www.sodreltrucklines.com	Contract Carrier	None
Stericycle, Inc.	2355 Waukegan Rd, Bannockburn, IL 60015	(847) 367-5910	www.Stericycle.com	Hazardous Waste Transporter	None
Tri-State Motor Transit Co.	8141 E 7th St, Joplin, MO 64801	(877) 860-1600	https://tristatesecured.com/	Contract Carrier	None
United Parcel Service, Inc.	55 Glenlake Parkway NE, Atlanta, GA 30328	(800) PICK-UPS	www.UPS.com/	Carrier	Closed Case 9/18/2019 VA-2019-0057-US1436"
United States Postal Service	475 L'Enfant Plaza SW, Washington, DC 20260	(202) 268-2000	www.USPS.com/	Carrier	See USPS SEC filings

Name	Address	Phone	Website	Type	Penalty Record (5 years)
Waste Recovery Solutions, LLC	343 King St, Myerstown, PA 17067	(336) 683-0809	www.covanta.com	Hazardous Waste Transporter	None

D. Disposal Facilities

Name	Address	Phone	Website	Type	Penalty Record (5 years)
Clean Harbors Aragonite, LLC	11600 North Aptus Rd, Grantsville, UT 84029	(435) 884-8900	www.cleanharbors.com	Hazardous Waste Incinerator	See Appendix E
Curtis Bay Energy, LP	3200 Hawkins Point Road, Baltimore, MD 21226	(855) 228-1715	www.curtisbayenergy.com	Medical Waste Incinerator	See Appendix E
Heritage Thermal Services – Ohio	1250 Saint George Street, East Liverpool, OH 43920	(800) 545-7655	http://www.heritagethermal.com/	Hazardous Waste Incinerator	See Appendix E
Indianapolis Resource Recovery Facility in Indiana, operating as Covanta Indianapolis, Inc.	2320 S. Harding St., Indianapolis, IN 46221	(371) 634-7367	https://www.covanta.com/where-we-are/our-facilities/in-indianapolis	Municipal Waste Combustor	See Appendix E

Name	Address	Phone	Website	Type	Penalty Record (5 years)
Lancaster County Waste to Energy Facility	1911 River Road, Bainbridge, PA 17502	(717) 397-9968	www.covanta.com	Municipal Waste Combustor	See Appendix E
Ross Incineration Services, Inc.	36790 Giles Road, Grafton, OH 44044	(440)-748-5800	http://www.rossenvironmental.com/	Hazardous Waste Incinerator	See Appendix E
Stericycle, Inc., Warren, Ohio Facility	1901 Pine Avenue S.E., Warren, OH 44483	(330) 393-0370	https://www.stericycle.com/service-locations/ohio/warren	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.

Educational materials are updated as needed and use plain language and explanatory images to promote consumer education and collection options to Residents with limited English proficiency and 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 from 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.

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)⁴; 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;

⁴ For Kiosk Drop-Off Site collection, only certain substances “that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected.” DEA Rule §1317.75(b). This language is similar to, but slightly different than, provisions limiting collection at Take-Back Events and through Standard Mail-Back Services to ultimate users or other persons (lawfully) entitled to dispose of an ultimate user decedent’s property. See DEA Rule §§ 1317.65(d); 1317.70(b).

- Provides for the use of mail-back programs to collect controlled substances;
- Allows for the commingling of controlled and non-controlled substances;
- Establishes detailed collection, recordkeeping, security, and other measures for all approved collection methods; and
- Provides that all collected pharmaceutical products be destroyed so that the products are rendered non-retrievable.

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

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

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 Services Center	222 Paul Scannell Drive	San Mateo	94402
County of San Mateo Probation South San Francisco	1024 Mission Road	South San Francisco	94080
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

Account Name	Street Address	City	Zip/Postal Code
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
Hillsborough Police Department	1600 Floribunda Avenue	Hillsborough	94010
Kaiser Daly City 1FI OP Pharmacy 341	395 Hickey Boulevard 1st Fl	Daly City	94015
Kaiser Redwood City Marshall MOB OP Pharmacy 370	905 Maple Street,FL 1 RM 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 (NEMS)Eastmoor Pharmacy	211 Eastmoor 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

Account Name	Street Address	City	Zip/Postal Code
San Mateo County Sheriff's Office - Coastside Patrol Bureau	500 California Avenue	Moss Beach	94038
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 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 Department	1 Chestnut Avenue	South San Francisco	94080
Sunshine Center Pharmacy	1166 Mission Road	South San Francisco	94080

Appendix B

Sample Kiosk and Signage



Sample Kiosk Signage

Front Panel Kiosk Art

SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE

- 

1 Cross out or remove personal identifying information from the medicine packaging.
- 

2 Leave the product in its original container or place solid medicine in a sealed plastic bag.
If transferring medication to a sealed bag, please be sure to recycle remaining packaging.
- 

3 Put medicine in the kiosk.

Only schedule II-V controlled and non-controlled substances that are lawfully possessed by the ultimate user are acceptable to be placed in the kiosk. Schedule I controlled substances, illicit or dangerous substances, and any controlled substances not lawfully possessed by the ultimate user may not be placed in the kiosk.

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

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

MED-ProjectTM
Medication Education & Disposal

USA/KI-01-0000003-SCA-01-02-41-0100

Sample Kiosk Signage

Side Panel Kiosk Art

The image shows a sample kiosk signage for safe medicine disposal. It features a blue background with large, bold text in yellow and white. Below the text are six icons representing various types of medications: a bag of pills, a pill bottle, a tube of cream, an inhaler, a pink medicine bottle, and a blister pack. At the bottom of the sign, contact information for the MED-Project Call Center is provided.

SAFELY DISPOSE OF EXPIRED OR UNWANTED MEDICINE



MED-Project Call Center: 1 (844) MED-PROJECT
1 (844) 633-7765 / (TTY: 711)
www.med-project.org

MED-Project[™]
Medication Education & Disposal

00000000000000000000000000000000

Sample Kiosk Signage

Drop-Slot Kiosk Art



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



NOT ACCEPTED: Herbal remedies, vitamins, cosmetics, batteries, mercury-containing thermometers, sharps, and illicit drugs.



Please separate and remove any medication listed as not accepted before disposing.

USA.KD.01.000200.ALL.01.04.43.01.00

Name: 123 Pharmacy

Contact: (555) 555-5555

USA.KA.01.000001.ALL.01.01.45.02.00

Appendix C

C 1: MED-Project request for approval to utilize municipal waste combustors for unwanted medicine disposal

MED-PROJECT REQUEST FOR APPROVAL TO UTILIZE MUNICIPAL WASTE COMBUSTORS FOR UNWANTED MEDICINE DISPOSAL

Under the County of San Mateo Safe Medicine Disposal Ordinance (the “Ordinance”), “[p]roposed changes to an approved Stewardship Plan that substantively alter plan operations, including, but not limited to... disposal facilities, must be approved in writing by the Director before the changes are implemented.” See Ordinance § 4.116.120(a). This request for approval is submitted pursuant at least 30 days prior to any change is scheduled to occur. Ordinance § 4.116.070(b) allows the Director to grant approval for the disposal of some or all collected covered drugs at a permitted large municipal waste combustor if the Director “deems the use of a hazardous waste disposal facility... to be infeasible for the Stewardship Plan Based on cost, logistics or other consideration”. Additionally, § 4.116.070(c) of the Ordinance permits the Director to approve the use of differing disposal technologies that provide “equivalent protection at lesser cost.” The Ordinance allows the Department to “exercise reasonable discretion to waive strict compliance with the requirements of this Chapter that apply to Producers in order to achieve the objectives of this Chapter.” See Ordinance § 4.116.110(f)

With these requirements and the objectives of the Ordinance in mind, MED-Project requests that the Department approve the use of any permitted municipal waste combustor for all Unwanted Medicine collected under the Plan. Municipal waste combustors provide equivalent protection of the public and environment as required by the Ordinance. In conjunction with this substantive change request, MED-Project is providing the Department with a May 16, 2022 memorandum prepared by ERM (the “ERM Memorandum”) at the request of MED-Project which provides a comprehensive comparison of different disposal facility technologies, including hazardous waste incinerators, medical waste incinerators, and municipal waste combustors, and demonstrates that medical waste incinerators and municipal waste combustors provide equivalent protection including in the four categories required by the Ordinance: monitoring of any emissions or waste; worker health and safety; reduction or elimination of air, water or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and overall impact on the environment and human health¹, See Appendix C-2

¹ The May 16, 2022 Memorandum was prepared in response to a similar petition in a different jurisdiction, however all included information is relevant for this request. The memorandum provides summaries of the environmental, health, and safety protections in place at the municipal waste combustors that MED-Project currently uses for other programs. This is intended to demonstrate the controls typically in place at municipal waste combustors for the purpose of supporting MED-Project’s request for approval of the use

1. The Use of Municipal Waste Combustors to Dispose of Unwanted Medicine Should be Approved Under § 4.116.070(b)-(c).

MED-Project proposes to use municipal waste combustors to dispose of unwanted medicine under §§ 4.116.070(b)-(c) of the Ordinance, because exclusive disposal at hazardous waste incineration facilities is not feasible based on cost, logistics, and other considerations and municipal waste combustors provide equivalent protection. Use of these municipal waste combustors would protect and preserve public and environmental health, consistent with the objectives of the Ordinance.

a. Approval of Municipal Waste Combustors for Disposal of Unwanted Medicine Will Provide Necessary Logistical Flexibility.

MED-Project has engaged multiple vendors to provide a comprehensive and reliable suite of services to the residents of the County of San Mateo, as ensuring the reliability and consistency of services requires using a variety of disposal facilities and vendors. For the disposal of unwanted medicine, MED-Project relies on Stericycle Specialty Waste Solutions, Inc. (“Stericycle”) and Covanta Environmental Solutions, LLC (“Covanta”) in order to ensure redundancy of services in case either vendor’s services are unavailable at any time, to control costs, to maintain flexibility, and to provide multiple options for the provision of these services. Stericycle and Covanta currently offer disposal of unwanted medicine at hazardous waste incinerators, medical waste incinerators, and municipal waste combustion facilities, but exclusive use of hazardous waste incinerator facilities for waste collected by the San Mateo Drug Takeback Program would limit the number of facilities available to MED-Project for the purposes described above and would increase costs as discussed further below. The special logistics required by the reverse distributors in order to ensure the waste collected from San Mateo is directed only to hazardous waste incinerator facilities creates additional complexity that can lead to logistical distribution discrepancies. Additionally, the limited capacity of the network of hazardous waste incinerator facilities is well documented² which can cause unexpected cancellation of waste shipments by hazardous waste facilities, resulting in the potential for not meeting Drug Enforcement Administration requirements for the destruction of unwanted medicine within the required thirty-day time limit.

b. Approval of Municipal Waste Combustors will Provide Significant Cost Savings.

of any municipal waste combustors as a disposal method for covered medicines, and is not meant to limit approval to these facilities.

² See, e.g., United States Environmental Protection Agency Memorandum dated August 10, 2021 from Director Carolyn Hoskinson, Re: Regulatory Options for Addressing [the Temporary Backlog of Containerized Hazardous Waste Needing Incineration](#).

The cost to dispose of unwanted medicine at hazardous waste incinerators is much greater than the cost to dispose of unwanted medicine at municipal waste combustors. In MED-Project's experience, hazardous waste incinerators typically charge significantly more than other incinerators to dispose of the same quantity of waste.³ Compliance, logistical feasibility, cost, and other considerations typically drive how MED-Project and its vendors select disposal facilities, and MED-Project appreciates the flexibility to respond to those factors and others as it operates its program with a variety of disposal options.

c. Municipal Waste Combustors Provide Equivalent Environmental, Health and Safety Protections.

Municipal waste combustors protect and preserve public health, safety, and welfare. Municipal waste combustors are subject to a number of environmental permitting requirements, consistent with the Ordinance's underlying objective of protecting and preserving public health, safety and welfare. For example, the municipal waste combustors described below and in the ERM Memorandum have Title V air permits and have installed extensive pollution control techniques, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, nitrogen oxide control systems, mercury control systems, and continuous emissions monitoring systems. The facilities identified are waste-to-energy facilities, which avoid the production of the greenhouse gas methane while producing electricity. Many of these facilities have also been recognized for their workplace safety achievements, as evidenced by their designation as VPP Star facilities. As outlined further in the ERM Memorandum, municipal waste combustors provide equivalent protection in each of the areas required by the Ordinance: monitoring of any emissions or waste; worker health and safety; reduction or elimination of air, water, or land emissions contributing to bioaccumulative, and toxic pollution, and overall impact on the environment and human health.

Below, we describe some of the environmental, health, and safety protections in place at the municipal waste combustors MED-Project currently proposes to use. These summaries are intended to demonstrate the controls typically in place at municipal waste combustors for the purpose of supporting MED-Project's request for approval of the use of any municipal waste combustor as a disposal method for unwanted medicine.

i. Covanta Indianapolis Facility

³ The May 16, 2022 Memorandum was prepared in response to a similar petition in a different jurisdiction, however all included information is relevant for this request. The memorandum provides summaries of the environmental, health, and safety protections in place at the municipal waste combustors that MED-Project currently uses for other programs. This is intended to demonstrate the controls typically in place at municipal waste combustors for the purpose of supporting MED-Project's request for approval of the use of any municipal waste combustors as a disposal method for covered medicines, and is not meant to limit approval to these facilities.

The Covanta Indianapolis Facility is a “waste-to-energy” facility that incinerates waste and generates up to 3.2 billion pounds of steam annually, providing 50% of the steam for downtown Indianapolis’ heating loop.⁴ The Covanta Indianapolis Facility employs semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system.

ii. Lancaster County Resource Recovery Facility

The Lancaster County Resource Recovery Facility in Pennsylvania (“Lancaster Facility”) is a permitted large municipal waste combustor. The Lancaster Facility is a “waste-to-energy” facility that incinerates waste and generates 33 megawatts per day from a condensing steam turbine.⁵ The Lancaster Facility employs semi-dry flue gas scrubber injecting lime, fabric filter baghouses, a furnace dry-lime inject system, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system.⁶ The Lancaster Facility operates under a Title V Clean Air Act permit and a solid waste permit. The Lancaster Facility is a “zero discharge” facility, meaning that the wastewater generated on-site is treated and reused in the waste management process, according to the facility’s website. The Lancaster Facility has been designated as a VPP Star facility by OSHA.

d. The Use of Municipal Waste Combustors for Disposal of Unwanted Medicine is Permitted under State and Federal Law and Approved by Numerous Jurisdictions.

There are no other laws or requirements, outside of the Ordinance, that would require MED-Project to dispose of unwanted medicine at a hazardous waste incinerator or preclude MED-Project from disposing of these materials at a municipal waste combustor. In fact, the U.S. Environmental Protection Agency (“EPA”) has issued a memorandum stating clearly that collected household pharmaceuticals are not subject to federal hazardous waste regulations, and can be sent to large and small municipal waste combustors.⁷ Any unwanted medicine collected by MED-Project under this Plan is not regulated under state or federal hazardous waste regulations, and therefore are not required to be treated as hazardous waste. Under United States Drug Enforcement Administration and EPA requirements, municipal waste combustors permitted for household medical waste are authorized to take materials from all jurisdictions in the United States. MED-Project’s understanding is that this is common practice across the United States. California’s Pharmaceutical and Sharps Waste Stewardship law, SB 212,

⁴ See Covanta, Covanta Indianapolis, <https://www.covanta.com/where-we-are/our-facilities/indianapolis>
See Covanta, Covanta Lancaster, <https://www.covanta.com/where-we-are/our-facilities/lancaster>

⁵ See Covanta, Covanta Lancaster, <https://www.covanta.com/where-we-are/our-facilities/lancaster>

⁶ *Id.*

⁷ See Memorandum on Management of Household Pharmaceuticals Collected by Law Enforcement During Take-Back Events and Programs, from Barnes Johnson, Office of Resource Conservation and Recovery, to RCRA Division Directors, EPA Regions 1-10 (Sep 11, 2018).

allows the use of municipal waste combustor technology for disposal of unwanted medicine. In addition, the disposal of unwanted medicine kiosk waste at municipal waste combustor facilities is approved in many other jurisdictions with product stewardship takeback laws, such as: The State of California, Alameda County, CA; Santa Barbara County, CA; San Luis Obispo, CA; City of Capitola, CA, City of Santa Cruz, CA; City of Scotts Valley, CA; and the State of Maine, State of New York, State of Oregon, and the State of Washington. As demonstrated above, MED-Project disposes of unwanted medicine from other nearby jurisdictions at municipal waste combustors, and any variation in the county of San Mateo would disrupt the existing waste management network across MED-Project's programs.

2. Conclusion

For the above reasons, the Department should use its discretion under §§ 4.116.110 and 4.116.070 of the Ordinance and approve the disposal of Unwanted Medicine at municipal waste combustors.

C 2: May 16, 2022, ERM Combined Incinerator Memo Final

ERM

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Date 16 May 2022
Client Jim Wilson, P.E.
Lead Director, Legal and Compliance
Med-Project
Reference Project No. 0572758
Subject ERM Review of Select Municipal Waste Combustors, Medical Waste
Incinerators, and Hazardous Waste Incinerators



INTRODUCTION

ERM was contracted by MED-Project to complete a comparison of incineration technologies at eight facilities across six different factors: cost, logistics, monitoring of any emissions or waste, worker health and safety, reduction or elimination of air, water, or land emissions contributing to persistent, bio-accumulative, and toxic pollution, and overall impact on the environment and human health. The facilities included in this comparison are:

- Stericycle, a Hospital Medical Infectious Waste Incinerator (HMIWI) located in Warren, Ohio with one unit that has a maximum waste material feed rate of 6,720 tons per year¹;
- Covanta Indianapolis, a municipal waste combustor, located in Indianapolis, Indiana with three units that have a design capacity of 264,990 tons per year of municipal solid waste per unit¹;
- Covanta Lancaster, a municipal waste combustor, located in Lancaster, Pennsylvania with three units that can process up to 146,000 tons per year of municipal solid waste per unit¹;
- Covanta York, a municipal waste combustor, located in York, Pennsylvania with three units that can process up to a combined 490,560 tons per year of municipal solid waste¹;
- Heritage Environmental, a hazardous waste combustor located in East Liverpool, Ohio with one incineration unit that can treat a total of 88,000 tons per year of hazardous waste¹;
- Ross Incineration, a hazardous waste combustor located in Elyria, Ohio with one incineration unit that has a total maximum waste feed rate of 114,130 tons per year¹;
- Clean Harbors Aragonite, a hazardous waste combustor located in Dugway, Utah with one incineration unit that has a current permitted capacity of approximately 113,880 tons per year¹; and
- Veolia Port Arthur, a hazardous waste combustor located in Port Arthur, Texas with one incineration unit that is permitted to handle up to 150,000 tons per year¹.

¹ Information available from publicly available websites.

A tabular format of the comparison is also included, attached to this memo in Appendix A.

COST

Stericycle indicated that the cost of medical waste incineration is averaging 2.8 times per pound lower than hazardous waste incineration². Municipal waste combustion is estimated to be 4 to 7 times less expensive than hazardous waste incineration on the east coast³.

LOGISTICS

All eight facilities accept Drug Enforcement Administration (DEA) controlled substances and non-RCRA pharmaceutical wastes collected at secure kiosks. Additionally, all of the facilities have indicated that there are no other limitations or prohibitions on specific medicine that they can handle.

Reverse distributed unwanted medicine boxes and liners must be sent to a DEA registered reverse distributor site before transfer to a destruction facility. For the purpose of this memo, it was assumed that all boxes and liners would be sent from San Francisco to the DEA registered reverse distributor site in Warren, Ohio before being sent to one of the eight destruction facilities. The Warren reverse distributor site is approximately 2,600 miles away from the San Francisco area; this mileage is accounted for in the greenhouse gas (GHG) calculations for all eight sites in the table in Appendix A.

The closest destruction facility is located in Warren, Ohio at the same location as the reverse distributor. The other seven facilities are located between 50 and 1,900 miles from the Warren, Ohio reverse distributor site, with the next closest facility, Heritage Environmental, being approximately 51 miles away and the furthest facility, Clean Harbors Aragonite, being approximately 1,835 miles away. Assuming diesel trucks are used to ship the waste, a Greenhouse Gas (GHG) emission factor of 3.64 pounds per mile travelled per vehicle, based on 2019 data from the EPA SmartWays Carrier Performance Rankings, was used to estimate GHG emissions associated with travel to each facility. Transportation to Stericycle Warren, the closest facility, would emit approximately 4.73 tons of CO_{2e} per one-way trip per vehicle.

Since as early as June 2021, many commercial hazardous waste incinerators have been unable to accept additional containerized hazardous waste designated for incineration due to a backlog at their facilities. This backlog has been caused by a number of factors, including labor shortages due to the COVID-19 pandemic, scheduled and unscheduled shutdowns due to maintenance and weather, and increased manufacturing and waste generation as the economy ramps up after the pandemic. EPA became aware of this problem and issued a memo titled "Regulatory Options for Addressing the Temporary Backlog of Containerized Hazardous Waste Needing Incineration" on August 10, 2021. A copy of this memo is included in Appendix D. Based on information collected by the EPA, the memo indicated that the backlog may not be fully resolved until the end of the first quarter of 2022.

Because of the backlog at hazardous waste incinerators and resulting extended storage requirements, it may be prudent for generators of non-hazardous wastes, which includes non-RCRA pharmaceuticals and non-hazardous DEA controlled substances, to avoid using hazardous waste incinerators. Facilities like municipal waste combustors and HMIWIs offer similar handling treatments for non-hazardous waste without adding to the backlog.

²Information provided in Stericycle draft letter to San Francisco Environment dated October 5, 2020.

³Information provided by Covanta in email dated January 27, 2021 to MED-Project at MED-Project's request.

MONITORING OF ANY EMISSIONS OR WASTE

Air Emissions

Stericycle utilizes a selective non-catalytic reduction system (SNCR), condensing absorber scrubber, venturi scrubber, mist eliminator, and carbon bed adsorber to reduce air emissions. Stericycle did not provide a destruction and removal efficiency (DRE) of their combustion unit, as DRE is a measure relevant for the destruction of hazardous constituents, which is not applicable to their facility².

The air pollution control equipment at Covanta Indianapolis includes the SNCR, a spray dry absorber, fabric filter, mercury emission control system, and a dustmaster conditioning system. Covanta Indianapolis indicated that their combustion process has a 99.9% destruction of pharmaceuticals and personal care products, but did not provide the method of calculation or a measure of DRE for their combustion units⁴.

Covanta Lancaster uses a dry lime injection system, SNCR, activated carbon system, dry scrubber, and a baghouse to reduce air emissions. Air pollution control equipment at Covanta York includes a lime spray dryer absorber, a fabric filter, and an activated carbon injection system on each incinerator unit. Neither Covanta Lancaster nor Covanta York provided a measure of DRE for their combustion units. Similar to the Stericycle operation, none of the three Covanta facilities handles hazardous waste at their facility and DRE is not applicable per regulatory requirements⁵.

Emission control equipment used at Heritage Environmental includes an electrostatic precipitator, 4-stage wet scrubber, carbon injection system, and a spray dryer. The Heritage incinerator demonstrated a destruction and removal efficiency of 99.9999% using EPA Method 3000 during a performance test conducted in March 2020⁶.

Ross Incineration uses a cyclone separator, radial flow scrubber, gas-liquid contactor, and two electrostatic precipitators as part of their air pollution control equipment. The air permit held by Ross Incineration requires a 99.99% destruction and removal efficiency for each principal organic hazardous constituent. The permit requires a one-time DRE test and only requires a retest if the combustion system is modified such that the DRE could be impacted. Ross Incineration did not provide a tested destruction and removal efficiency of their combustion unit nor a method used for calculation⁵.

Clean Harbors Aragonite uses a spray dryer, baghouse, saturator, and wet scrubber to reduce air emissions from the incinerator. Based on information provided by Clean Harbors Aragonite, the incinerator demonstrated a 99.99999% DRE using SW-846 Method 0023A to sample train and SW-846 Method 8270 to analyze during its most recent performance test⁵.

Veolia Port Arthur control equipment includes a wet scrubber and wet electrostatic precipitator. A minimum of 99.99% DRE for organic hazardous constituents and 99.8% DRE for hydrogen chloride is required for the incinerator⁵.

The Table 1 below lists emission rates at each facility based on most recent actual test results of the incinerators at Stericycle, Covanta Indianapolis, Covanta Lancaster, Covanta York, and

⁴ Information provided from Covanta Indianapolis Title V permit dated November 4, 2019.

⁵ Information publically available on facility websites.

⁶ Information based on publically available documents in Ohio EPA's eDocument Search.

Heritage Environmental. Ross Incineration did not provide actual emission rates for their facility. Table 2 lists the pollutant limitations for all eight facilities.

Table 1. Actual Emission Rates of Select Pollutants at Each Facility

Pollutant, units	Stericycle ⁷	Covanta Indianapolis ⁸	Covanta Lancaster ⁸	Covanta York ⁸	Heritage ⁵	Ross Incineration	Clean Harbors Aragonite ⁹	Veolia Port Arthur ⁹
Particulate, grains/dscf	0.0012	0.0027	0.0002	0.0003	0.001	Actual emission rates not provided. See Table 2 for pollutant limits.	0.0022	NA
Particulate, tpy	NA	NA	NA	NA	NA		NA	0.6084
Nitrogen Oxides, ppmv	117.7	143	142.3	119.3	NA		NA	NA
Nitrogen Oxides, tpy	NA	NA	NA	NA	72.96		108.07	107.23
Carbon Monoxide, ppmv	0.4	44.3	10.4	55.7	11		42.18	NA
Carbon Monoxide, tpy	NA	NA	NA	NA	NA		NA	0.6891
Sulfur Dioxide, ppmv	0.12	8.7	0.7	14.3	NA		11.35	0.25
Sulfur Dioxide, tpy	NA	NA	NA	NA	4.99		20.63	1.3271
Hydrogen Chloride, ppmv	0.0599	8.3	1.3	1.0	0.13		1.8	NA
Hydrogen Chloride, tpy	NA	NA	NA	NA	NA		NA	0.9080
Cadmium, mg/dscm	0.0002	0.0012	0.0002	0.0002	0.014		0.092	NA
Lead, mg/dscm	0.0019	0.0101	0.0031	0.0025			NA	0.0025
Cadmium & Lead, tpy	NA	NA	NA	NA	NA		NA	0.0025
Mercury, mg/dscm	0.0029	0.0007	0.0004	0.0008	0.014		0.046	NA
Mercury, tpy	NA	NA	NA	NA	NA		NA	0.0145
Total Dioxins/Furans, ng/dscm	0.0772	1.4	0.5	1.3	0.03		0.0069	0.099
TEQ Dioxins/Furans, ng/dscm	0.001	Not Provided	Not Provided	Not Provided	0.03		0.0069	0.0077

⁷ Information provided in draft Stericycle letter to San Francisco Environment dated October 5, 2020.

⁸ Information provided by Covanta in email dated December 3, 2020 to MED-Project at MED-Project's request.

⁹ Information provided by MED-Project in a spreadsheet dated December 21, 2021.

Waste Generated

Ash generated at each facility is managed via landfilling.

Ash generated at Stericycle is sent to a non-hazardous (Subtitle D) landfill. Ash is sampled and analyzed quarterly for metals to ensure that it meets all governing regulations (e.g., does not exhibit a hazardous waste characteristic). On average, Stericycle produces approximately 1,300 tons of ash per year¹⁷.

Covanta Indianapolis uses advanced magnets and eddy current separators to remove ferrous and non-ferrous metals from the ash prior to disposal. Approximately one-third of the ash generated at Covanta Indianapolis is sent to a municipal solid waste landfill, where it is used as daily cover. The remaining ash is sent to an ash monofill, which is a non-hazardous landfill that contains only ash. Based on current operations, the amount of ash generated is equal to about 25% of the weight of the initial waste¹⁸.

At Covanta Lancaster, ferrous and non-ferrous materials are removed from the ash generated and recycled. The remaining ash is then taken to a nearby non-hazardous landfill and used as daily cover. Ash generated is equal to approximately 10% of the initial waste volume¹⁸.

Ash generated at Covanta York is sent next door to the Ash Recycling and Processing Facility (ARPF) for furthering processing. The ARPF uses a wet separation technology to increase the recovery of recyclable materials, including aggregates, metals, and sand from the ash. Any ash remaining after processing at the ARPF is managed at a landfill. Approximately 10% of the initial waste volume remains as ash for landfilling¹⁸.

Heritage Environmental generates waste salt and slag that is landfilled in a hazardous waste landfill. In 2019, the Heritage Environmental incinerator generated just over 18,000 tons of residuals that were disposed in an offsite hazardous waste landfill. The most recent biennial waste report from 2017 indicates that Heritage Environmental received approximately 53,700 tons of waste; the amount of ash generated is equal to about 33.5% of the weight of the initial waste received¹⁸.

Ross Incineration chemically solidifies the ash generated from the incinerator to bind metals into a concrete-like substance and then the solidified ash is disposed in an offsite hazardous waste landfill. No information was provided on the amount of residuals generated at Ross Incineration¹⁸.

Clean Harbors Aragonite and Veolia Port Arthur both send generated ash for landfilling at Subtitle C RCRA landfills. Clean Harbors Aragonite generated 20,074 tons of waste in 2020¹⁹. Veolia Port Arthur generated 2,100 tons of waste, including residuals that were shipped offsite¹⁹.

Water Emissions

Stericycle has onsite wastewater pretreatment, which includes a series of settling and separation tanks and filters. The pretreated wastewater is then discharged to a Publicly

¹⁷ Information provided in draft Stericycle letter to San Francisco Environment dated October 5, 2020.

¹⁸ Information provided from publically available websites.

¹⁹ Information provided by MED-Project in a spreadsheet dated December 21, 2021.

Operated Treatment Works (POTW). Stericycle holds a permit with the POTW to discharge the pretreated wastewater. Any wastewater sludge generated is subject to metal testing and is sent to a landfill for disposal. On average, Stericycle produces approximately 48 tons of wastewater sludge annually²².

Sewage sludge is generated at Veolia Port Arthur from an onsite wastewater treatment plant that treats domestic sewage generated onsite, unrelated to the hazardous waste operations. The generated sludge is sent offsite; approximately 92 tons of wastewater sludge is produced annually.

The six remaining facilities, Covanta Indianapolis, Covanta Lancaster, Covanta York, Heritage Environmental, Ross Incineration and Clean Harbors Aragonite indicated that they do not discharge any wastewater during their operations.

WORKER HEALTH AND SAFETY

OSHA 300 logs for the past three years were provided for review for Stericycle, Covanta Indianapolis, Covanta Lancaster, Covanta York, and Heritage Environmental²⁰. Ross Incineration, Clean Harbors Aragonite, and Veolia Port Arthur did not provide OSHA 300 logs for review.

Stericycle had four recordable injuries between 2017 and 2018, with no recordable injuries in 2019. Covanta Indianapolis had two recordable injuries in 2017, with no recordable injuries in 2018 and 2019. Covanta Lancaster had no record injuries between 2017 and 2019. Covanta York had no recordable injuries in 2017 and 2019, with two recordable injuries in 2018. Heritage Environmental had eight recordable injuries over the past three years. The provided OSHA 300 logs are attached to this memo in Appendix B.

Covanta Indianapolis, Covanta Lancaster, Covanta York, Clean Harbors Aragonite, and Veolia Port Arthur all participate in the OSHA voluntary participation program (VPP); Covanta Indianapolis is part of the Indiana state VPP, while the other facilities participate at the federal level²¹. The results of the most recent self-audit were not provided for any of the facilities.

REDUCTION OR ELIMINATION OF AIR, WATER, OR LAND EMISSIONS CONTRIBUTING TO PERSISTENT, BIO-ACCUMULATIVE, AND TOXIC (PBT) POLLUTION AND OVERALL IMPACT ON THE ENVIRONMENT AND HUMAN HEALTH

Metrics identified to quantify the reduction or elimination of air, water, or land emissions contributing to PBT pollution include the Toxic Release Inventory (TRI) reporting results from the four approved and proposed facilities that completed TRI reporting for the past three years. EPA's Risk Screening Environmental Indicators (RSEI) scores for the past three years were compiled for the four approved and proposed facilities that complete TRI reporting as an indicator of the overall impact on the environment and human health. Neither Stericycle, Covanta Indianapolis, Covanta Lancaster, nor Covanta York completed TRI reporting for the previous three years, based on a review of the EPA's TRI databases²¹.

²⁰ OSHA 300 logs for Stericycle and Heritage provided in email dated November 12, 2020 to MED-Project at MED-Project's request OSHA 300 logs for Covanta facilities provided in emails dated November 5 and December 3, 2020 to MED-Project at MED-Project's request.

²¹ Information from publicly available websites.

For the approved and proposed facilities that do not complete TRI reporting and do not have a RSEI score, alternative evaluation metrics for reduction or elimination of air, water or land emissions contributing to PBT pollution and overall impact on the environment and human health are required. In accordance with the April 30, 2021, request for additional information from the San Francisco Department of the Environment, a review of the underlying federal and state regulatory emission limits utilized as a basis for permitting of different types of Waste Incinerators/Combustors was performed in an effort to compare the level of emission control required for air emissions. This evaluation can be utilized as a relative assessment of operational requirements to control emission of certain regulated persistent, bio-accumulative, and toxic (PBT) constituents from each facility type, as well as represent overall impact on the environment and human health.

Toxic Release Inventory Reporting Results

As mentioned above, four of the eight facilities discussed in this memo do not complete TRI reporting.

The Stericycle facility has determined that it is not subject to TRI reporting, as it does not meet the required reporting criteria. Stericycle states that it does not manufacture, process, or use any chemicals that are found on the TRI List of Chemicals. Additionally, Stericycle's NAISC code (562213) only triggers TRI reporting for facilities that either take hazardous waste or are RCRA Subtitle C facilities, neither of which criteria applies to Stericycle.²² Covanta did not provide information regarding the applicability of TRI reporting for any of its three facilities.

Ross Incineration, Heritage Environmental, Clean Harbors Aragonite, and Veolia Port Arthur reported releases of nine different PBT chemicals and four different PBT chemical categories from their respective facilities between 2017 and 2019²¹.

Risk-Screening Environmental Indicators

EPA's Risk-Screening Environmental Indicators (RSEI) utilizes information from TRI data to determine a numeric score representing a potential for chronic human health risk. These RSEI can be used as a factor for determining overall impact on the environment and human health. Four of the facilities included in this memo, Stericycle, Covanta Indianapolis, Covanta Lancaster and Covanta York do not report for TRI and therefore, do not have a RSEI score²¹. Veolia Port Arthur had the highest RSEI score of the facilities that do report for TRI for all three years between 2017 and 2019. RSEI scores for the TRI reporting facilities are listed in Appendix A.

Permit Review Methodology

For the approved and permitted facilities that do not complete TRI reporting and therefore do not have an RSEI score, a review of the air permitting at each type of facility was completed as an alternative to quantify reduction or elimination of emissions contributing to PBT pollution and as an indicator of overall impact on the environment and human health.

The review utilized three permits as representative examples of each of the three types of facilities presented in ERM's prior comparison dated March 8, 2021. This included Hospital Medical Infectious Waste Incinerators (HMIWI) [40 CFR Part 62, Subpart HHH], Hazardous Waste Incinerators [40 CFR Part 61, Subpart C; 40 CFR Part 63, Subpart EEE, and Ohio State Regulations from Ohio Administrative Code (OAC) 3745-31-05(A)(3)] and Large

²² Information provided in draft Stericycle letter to San Francisco Environment dated October 5, 2020.

Municipal Waste Combustors [40 CFR Part 60 Subpart Eb and Pennsylvania Code 25 Pa. Code §127.441. Each type of facility evaluated is subject to Federal emission standards which provide a ceiling for operational emissions. Because these standards are applied across the facility type, relative comparison of the required emission limitation requirements of a representative facility within each type can be used to assess the control of certain types of PBT emissions for each overall type group.

The HMIWI emission limits reviewed were for the Large HMIWI (N001, Incinerator) under 40 CFR Part 62 Subpart HHH at the Stericycle Inc. facility in Ohio (Facility ID: 0278080634; Permit Number: P0128242).

The Hazardous Waste Incinerator (N001, Hazardous Waste Incinerator) emission limits reviewed were for the Heritage Thermal Services facility in Ohio (Facility ID: 0215020233; Permit Number: P0128768). The facility is regulated under 40 CFR Part 63, Subpart EEE as an existing source; under 40 CFR Part 61, Subpart C; and also, under (OAC) 3745-31-05(A)(3). These limits provide the regulatory required floor for operations of the facility. Additional facility specific operational requirements established during performance testing also are used in compliance.

The Municipal Waste Combustor emission limits reviewed for the Lancaster County Solid Waste Management Authority Susquehanna Resource Management Complex facility in Pennsylvania (Title V Permit No: 22-05007). This is a large category existing facility which operates under 40 CFR Part 60 Subpart Eb (For affected facilities that commenced construction, modification, or re-construction after September 20, 1994, and on or before December 19, 2005) and also under Pennsylvania Code 25 Pa. Code §127.441.

Regulatory Emission Limit Comparison

A short summary of the emission limits comparison is shown in the following table with the most stringent regulatory emission rates highlighted in red; a more detailed summary is provided in Appendix C.

Table 3. Regulatory Emission Limits for each type of Facility

Incinerator Category		HMIWI	Hazardous Waste Incinerator	Municipal Waste Combustor
Construction Date		On or before December 1, 2008		Constructed commenced after September 20, 1994 or modified or reconstructed after June 19, 1996
Sub-Category**		Large	Existing Sources	Facilities that commenced construction, modification, or reconstruction after September 20, 1994, and on or before December 19, 2005
Air Emission Rates of Selected Pollutants	Particulate, mg/dscm	25	29.75	24
	Carbon Monoxide ³ , ppmv	11	100	100
	Dioxins/furans, ng/dscm total dioxins/furans (ng/dscm TEQ)	9.3 (0.054)	--(0.2)	13--
	Hydrogen chloride ⁴ , ppmv	6.6	32	25
	Sulfur Dioxide, ppmv	9	11.34 (lb/hr)	30
	Nitrogen Oxides, ppmv	140	28.36 (lb/hr)	135 ⁵
	Lead ¹ , mg/dscm	0.036	0.23	0.166
	Cadmium ¹ , mg/dscm	0.0092		0.0158
	Mercury, mg/dscm	0.018	0.13	0.08
	Beryllium, g/24hr	---	10.0	---
	Beryllium ² , mg/dscm	---	0.092	0.0002
	Arsenic ² , mg/dscm	---		0.0072
Chromium ² , mg/dscm	---	0.0023		
Citations		40 CFR Part 62, Subpart HHH	40 CFR Part 61, Subpart C (Beryllium); 40 CFR Part 63, Subpart EEE; OAC rule 3745-31-05(A)(3)	40 CFR Part 60, Subpart Eb; 25 Pa. Code §127.441

**All concentration based emission limits are corrected to 7 percent oxygen on a dry basis

¹For hazardous waste incinerators, the emission limit is for the combined emissions of cadmium and lead [40 CFR 63.1219(a)(3)].

²For hazardous waste incinerators, the emission limit is for the combined emissions of arsenic, beryllium, and chromium [40 CFR 63.1219(a)(4)].

³For hazardous waste incinerators, if complying with 100 ppmv CO, you must document that during the DRE test runs hydrocarbons do not exceed 10 ppmv during runs. Otherwise, the facility must comply with a 10 ppmv hydrocarbon limit.

⁴For hazardous waste incinerators, the emission limit is for hydrogen chloride and chlorine gas (total chlorine) expressed as a chloride (Cl-) equivalent.

⁵Limit is voluntary limit for emission netting purposes.

The focus of this review on larger existing systems provides a realistic comparison of national waste handling capabilities regarding the overall impact on environment and human health. As noted in Appendix C, there are sub-categories for some of the regulations for existing and newly constructed facilities, and for some combustor types different requirements are based on capacity (small, medium, and large). Most waste combustion systems currently operating and available for use are existing facilities due to the general difficulty in obtaining permits for new facilities. In general, the new facilities have somewhat lower regulatory emissions criterion (e.g., the Stericycle facility in Warren Ohio), and smaller systems have higher emission allowances. Large facilities are generally preferable for national scope programs due to capacity, and their higher feed rates generally allow for more consistent operations. Consistent operations typically result in better performance and this is reflected in the lower emission rates codified in regulation for that category.

Data Observations

Although the different combustion systems manage different waste inputs, control and limitation requirements are required for similar classes of PBT air emission constituents. These include dioxin/furans, metals, acid gas, along with indicators of combustion efficiency such as carbon monoxide, particulates, and nitrogen oxides. The overall goal of these requirements is to establish and maintain conditions within the facility that result in destruction of the waste materials and minimize to the extent practical toxic emissions. However, the rate of allowed emission does vary to an extent between waste streams and facility type.

In general, the HMIWI reviewed has the most stringent emission limits based on applicable regulations noted in the facility permits, as can be seen in the table above. For the pollutants where the HMIWI regulations are not the most stringent they are extremely close to the next most stringent facility, which is the Municipal Waste Combustor. The least stringent regulatory emission limits reviewed were for the Hazardous Waste Incinerator. Based upon these regulatory comparisons, the combustor types that would typically be the most limiting of air emissions from combustion of waste would be the HMIWI and Large Municipal Waste Combustors.

However, beyond this focused comparison of regulatory detail, the capability of each category of waste combustor to effectively manage PBT constituents is a function of its technical configuration and operation. The larger combustion systems are able to incorporate and operate comprehensive emission control trains and their scale of operation tends to even out irregular waste streams providing consistent operational conditions. When evaluating HMIWI, municipal waste combustors, and hazardous waste incinerators, the individual operational scale, conditions, configurations, and compliance history are likely as informative of the ability of a facility to control PBT constituents as the regulatory class. A larger capacity well configured and operated facility in any of the three combustor classes evaluated should be effective for household medicine returns and medical waste destruction and provide for PBT management.

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 Penalty Records

Clean Harbors Aragonite, LLC

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 st , 2 nd , 3 rd , and 4 th quarters in 2017 and for the 2 nd 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

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

Facility Summary



HERITAGE THERMAL SERVICES

1250 ST. GEORGE STREET, EAST LIVERPOOL, OH 43920

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

-  [Enforcement Case Report](#)
 -  [Air Pollutant Report](#)
 -  [CWA Pollutant Loading Report](#)
 -  [CWA Effluent Charts](#)
 -  [EPA Facility Documents](#)
 -  [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 NC (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)
CAA	2	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, (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 (eGRT): [1001897](#)

Toxic Releases (TRI): 43920VNRLL1250S

Compliance and Emissions Data Reporting Interface (CEDRI): [CEDRI125535](#), [CEDRI90484](#)

Compliance Summary Data

Statute	Source ID	Current SNC/HPV	Current As Of	Qtrs with NC (of 12) ⓘ	Data Last Refreshed
CAA	OH0000000215020233	No	04/01/2023	7	03/31/2023
CWA	OH0107298	No	12/31/2022	0	03/31/2023
RCRA	OHD980613541	No	04/01/2023	0	03/31/2023
RCRA	OHR000220285	No	04/01/2023	0	03/31/2023

Three-Year Compliance History by Quarter ⓘ

[Download Data](#)

Statute	Program/Pollutant/Violation Type				QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12
CAA	CAA (Source ID: OH0000000215020233)				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	01/01-03/31/23
	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 Violation Identified
	HPV History															
	Violation Type	Agency	Programs	Pollutants												
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL						09/03/2021						
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021							
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/2022				
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL										09/23/2022		
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021							

Compliance Summary Data

Statute	Source ID	Current SNC/HPV	Current As Of	Qtrs with NC (of 12) ①	Data Last Refreshed
CAA	OH000000215020233	No	04/01/2023	7	03/31/2023
CWA	OH0107298	No	12/31/2022	0	03/31/2023
RCRA	OHD980613541	No	04/01/2023	0	03/31/2023
RCRA	OHR000220285	No	04/01/2023	0	03/31/2023

Three-Year Compliance History by Quarter ①

[Download Data](#)

Statute	Program/Pollutant/Violation Type				QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12+
CAA	CAA (Source ID: OH000000215020233)				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	01/01-03/31/23
	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 Violation Identified
	HPV History															
	Violation Type	Agency	Programs	Pollutants												
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL						09/03/2021						
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021							
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/2022				
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL										09/23/2022		
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021							

CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL								03/01/2022				
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL		09/11/2020										
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL					05/21/2021							
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL	05/15/2020											
CAA	FRV	OH	CAAMACT, CAANESH, CAANSPS, CAASIP, CAATVP	FACIL									06/03/2022			

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12	QTR 13+ ①
CWA	CWA (Source ID: OH0107298)	01/01-03/31/20	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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	Undetermined
	Quarterly Noncompliance Report History													

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12*
RCRA (Source ID: OHD980613541)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified
	Violation												
	Agency												
RCRA (Source ID: OHR000220285)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified
	Violation												
	Agency												

Informal Enforcement Actions Last 5 Years



Statute	System	Source ID	Type of Action	Lead Agency	Date
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	09/02/2022
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	05/13/2022
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	02/22/2022
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	11/08/2021
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	08/27/2021
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	05/12/2021
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	02/17/2021
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	11/24/2020
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	09/04/2020
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	05/11/2020
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	02/24/2020

CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	11/20/2019
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	08/27/2019
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	05/17/2019
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	02/27/2019
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	08/10/2018
CAA	ICIS-Air	OH0000000215020233	Notice of Violation	State	05/30/2018
RCRA	RCRAinfo	OHD980613541	WRITTEN INFORMAL	State	09/19/2019
RCRA	RCRAinfo	OHD980613541	WRITTEN INFORMAL	EPA	11/02/2018

Entries in italics are not counted as "informal enforcement actions" in EPA policies pertaining to enforcement response tools.

Formal Enforcement Actions Last 5 Years

Statute	System	Law/Section	Source ID	Type of Action	Case No.	Lead Agency	Case Name	Issued/Filed Date	Settlements/Actions	Settlement/Action Date	Federal Penalty Assessed	State/Local Penalty Assessed	Penalty Amount Collected	SEP Value	Comp Action Cost
CAA	ICIS-Air	112	AIR/OH0000000215020233	Judicial	05-2015-5085	EPA	HERITAGE -WTI	10/18/2018	1	04/01/2022	\$288,000	\$0	\$288,000	\$302,500	\$305,000

Indianapolis Resource Recovery Facility in Indiana operating as Covanta Indianapolis Inc.

Facility Summary



COVANTA ENERGY
 2320 S HARDING ST, INDIANAPOLIS, IN 46221
FRS ID: 110001351625
EPA Region: 05
Latitude: 39.7337
Longitude: -86.1888
Locational Data Source: EIS
Industries: Waste Management and Remediation Services
Indian Country: N

Related Reports

- A [Air Pollutant Report](#)
- L [CWA Pollutant Loading Report](#)
- D [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 NC (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)
RCRA	2	10/06/2022	No Violation Identified	1	0	2	--	--	--	--
CAA	3	08/18/2022	Violation w/in 1 Year	3	0	--	--	--	--	--
CWA	1	08/22/2018	Unknown	0	0	--	--	--	--	--

Regulatory Information

Clean Air Act (CAA): Operating Major (IN0000001809700123)
Clean Water Act (CWA): Minor, Permit Effective; Compliance Tracking Off (INRM01589)
Resource Conservation and Recovery Act (RCRA): Active SQG, (IND984882365)
Safe Drinking Water Act (SDWA): No Information
[Go To Enforcement/Compliance Details](#)
[Known Data Problems](#)

Other Regulatory Reports

Air Emissions Inventory (EIS): 7744611
Greenhouse Gas Emissions (eGRT): 1000293
Toxic Releases (TRI): No Information
Compliance and Emissions Data Reporting Interface (CEDRI): No Information


Three-Year Compliance History by Quarter

[Download Data](#)

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12+
CAA (Source ID: IN0000001809700123)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	Violation Identified	No Violation Identified	No Violation Identified	Violation Identified
HPV History													
	Violation Type	Agency	Programs	Pollutants									
CAA	FRV	IN	CAATVP	Carbon monoxide	09/29/2020								
CAA	FRV	IN	CAATVP	Carbon monoxide	05/20/2022								
CAA	FRV	IN	CAATVP	FACIL	01/17/2023								

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12+
CWA (Source ID: INRM01589)		01/01-03/31/20	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
	Facility-Level Status	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
	Quarterly Noncompliance Report History	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12+
RCRA (Source ID: IND984882365)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	Violation Identified	No Violation Identified
	Violation	Agency											
RCRA	279.C: Used Oil - Generators	IN	10/06/2022-11/15/2022										

Informal Enforcement Actions Last 5 Years 



Statute	System	Source ID	Type of Action	Lead Agency	Date
RCRA	RCRAInfo	IND984882365	WRITTEN INFORMAL	State	10/14/2022
RCRA	RCRAInfo	IND984882365	WRITTEN INFORMAL	State	07/09/2018

Entries in italics are not counted as "informal enforcement actions" in EPA policies pertaining to enforcement response tools.

Formal Enforcement Actions Last 5 Years 

Statute	System	Law/Section	Source ID	Type of Action	Case No.	Lead Agency	Case Name	Issued/Filed Date	Settlements/Actions	Settlement/Action Date	Federal Penalty Assessed	State/Local Penalty Assessed	Penalty Amount Collected	SEP Value	Comp Action Cost
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No data records returned

Lancaster County Waste to Energy Facility

Facility Summary



LANCASTER CNTY SWA TRASH INCINERATOR
 1911 RIVER ROAD, BAINBRIDGE, PA 17502
FRS ID: 110000925795
EPA Region: 03
Latitude: 40.071615
Longitude: -76.644086
Locational Data Source: EIS
Industries: Waste Management and Remediation Services
Indian Country: N

Related Reports

- Enforcement Case Report
- Air Pollutant Report
- [View Envirofacts Reports](#)

Enforcement and Compliance Summary

Statute	Compliance Monitoring Activities (5 years)	Date of Last Compliance Monitoring Activity	Compliance Status	Qtrs with NC (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)
CAA	3	12/29/2022	No Violation Identified	1	0	--	3	\$52,946	--	--
RCRA	--	--	No Violation Identified	0	0	--	--	--	--	--

Regulatory Information

Clean Air Act (CAA): Operating Major (PA000245684)
Clean Water Act (CWA): No Information
Resource Conservation and Recovery Act (RCRA): Active Other, (PA0000103713)
Safe Drinking Water Act (SDWA): No Information
[Go To Enforcement/Compliance Details](#)
[Known Data Problems](#)

Other Regulatory Reports

Air Emissions Inventory (EIS): 6581211
Greenhouse Gas Emissions (eGGRT): No Information
Toxic Releases (TRI): No Information
Compliance and Emissions Data Reporting Interface (CEDRI): No Information

Compliance Summary Data

Statute	Source ID	Current SNC/HPV	Current As Of	Qtrs with NC (of 12)	Data Last Refreshed
CAA	PA000245684	No	04/01/2023	1	03/31/2023
RCRA	PA0000103713	No	04/01/2023	0	03/31/2023

Three-Year Compliance History by Quarter

[Download Data](#)

Statute	Program/Pollutant/Violation Type	QTR 1	QTR 2	QTR 3	QTR 4	QTR 5	QTR 6	QTR 7	QTR 8	QTR 9	QTR 10	QTR 11	QTR 12+
CAA (Source ID: PA000245684)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified
	HPV History												
	Violation Type												
	Agency												
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
CAA	FRV	PA	CAASIP	FACIL			06/14/2021						
RCRA (Source ID: PA0000103713)		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	01/01-03/31/23
	Facility-Level Status	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified	No Violation Identified
	Violation												
	Agency												

Informal Enforcement Actions Last 5 Years



Statute	System	Source ID	Type of Action	Lead Agency	Date
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No data records returned

Entries in italics are not counted as "informal enforcement actions" in EPA policies pertaining to enforcement response tools.

Formal Enforcement Actions Last 5 Years

n	Law/Section	Source ID	Type of Action	Case No.	Lead Agency	Case Name	Issued/Filed Date	Settlements/Actions	Settlement/Action Date	Federal Penalty Assessed	State/Local Penalty Assessed	Penalty Amount Collected	SEP Value	Comp Action Cost
ir	OTHER	AIR/PA000245684	Administrative - Formal	PA000A0000E00000000399026	State	--	11/12/2021	1	11/12/2021	\$0	\$2,050	--	\$0	\$0
ir	OTHER	AIR/PA000245684	Administrative - Formal	PA000A0000E00000000395353	State	--	06/23/2021	1	06/23/2021	\$0	\$8,700	--	\$0	\$0
ir	OTHER	AIR/PA000245684	Administrative - Formal	PA000A0000E00000000363399	State	--	04/05/2018	1	04/05/2018	\$0	\$42,196	--	\$0	\$0

Ross Incineration Services, Inc.

YEAR	AGENCY	NOVs ISSUED	FINES PAID
2022	U.S. EPA	Finding of Violation proposed in 2020 regarding breakthrough on tank interfaces under the Benzene national Emission Standards for Hazardous Air Pollutants regulations.	Consent Agreement and Final Order requiring third party evaluation of Leak Detection and Repair programs and payment of \$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.

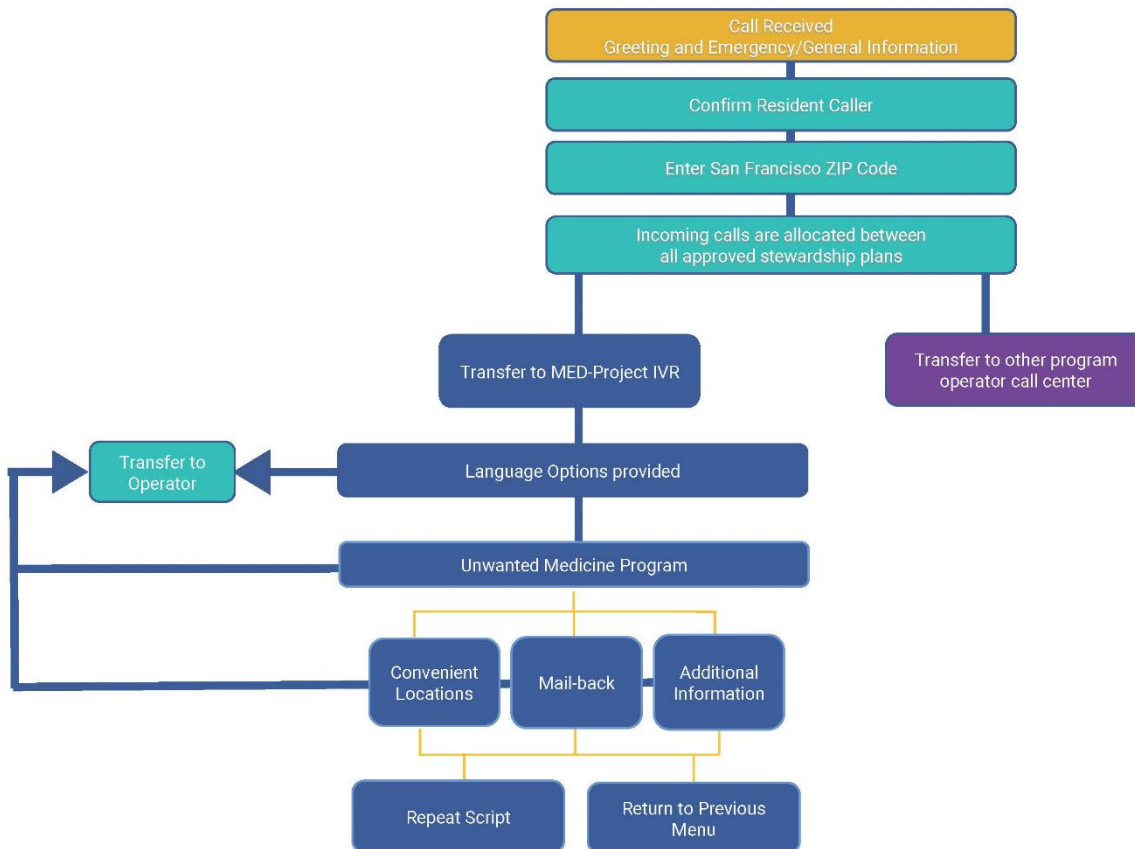
Appendix F

Sample Call Center Flow

MED-Project®

Medication Education & Disposal

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



Appendix G

Sample MED-Project Website Pages

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 mail-back 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. However, if you have expired or unwanted **medicines**, proper disposal is important and easy.

[Learn more about the program](#)



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services



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Medicine Usage



Follow safe disposal instructions if found on label, package, or package insert.

Adhering to your medication routine means taking your medicine as directed or as prescribed – the right dose, at the right time, in the right way.

Never dispose of medication down the sink or toilet unless directed.

If you have questions about any medication or your health, please contact your healthcare provider.



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Safe Storage Information



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.



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Find A Location



Convenient Locations What Can I Dispose Of Location Services

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 convenient location near you.

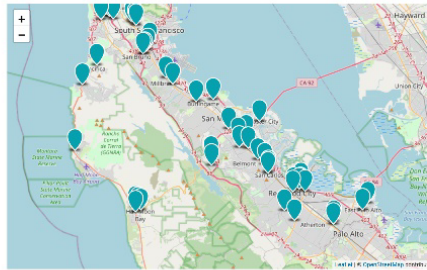
Starting Point Radius

Zip Code 5 Miles

Zip Code Address

Filter Results

- Select All
- Medicine Kiosks



Location Information

Menlo Park Police Department

701 Laurel Street
Menlo Park, CA, 94025

[Get Directions](#)

(650) 330-6300

Services Provided	Hours of Operation
Medicine Kiosks	Monday 7:30 AM - 5:30 PM Tuesday 7:30 AM - 5:30 PM Wednesday 7:30 AM - 5:30 PM Thursday 7:30 AM - 5:30 PM Friday 8:00 AM - 5:00 PM

Daly City Police Department

333 90th Street
Daly City, CA, 94015

[Get Directions](#)

(650) 991-8119

Services Provided	Hours of Operation
Medicine Kiosks	Monday 8:00 AM - 6:00 PM Tuesday 8:00 AM - 6:00 PM Wednesday 8:00 AM - 6:00 PM Thursday 8:00 AM - 6:00 PM Friday 8:00 AM - 6:00 PM Saturday 8:00 AM - 12:00 PM

[Load More Results](#)

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 Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Find A Location



[Convenient Locations](#) ▲ [What Can I Dispose Of?](#) ▲ [Location Services](#) ▼

Location Services

See descriptions of our services below.



Medicine Kiosks

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.



Medicine Usage



Safe Storage Information



Find a Location



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Find A Location



- Convenient Locations ▲
- What Can I Dispose Of? ▼**
- Location Services ▲

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.

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
- Medical devices
- Batteries
- Mercury-containing thermometers
- Sharps
- Illicit drugs

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



Medicine Usage



Safe Storage Information



Find a Location



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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. 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* Last Name*

Email

Address*

Apt #, Building #, Suite #

City* CA Zip Code*

* Required field

Submit Request

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

Accepted Medicine

Accepted: Medication in any dosage form, except for those identified as not accepted below, in their original container or sealed bag are accepted.

- 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 Inhalers

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.

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.



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Learn



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.



Brochure - Medicine Program

[View Brochure](#)



Frequently Asked Questions

[View our FAQs](#)



Video Public Service Announcement (PSA) – Medicine Program

[Watch PSA](#)



Survey Information & Results

[View Survey](#)

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



[Medicine Usage](#)



[Safe Storage Information](#)



[Find a Location](#)



[Mail-Back Services](#)

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Brochure



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



Find a Location



Mail-Back Services

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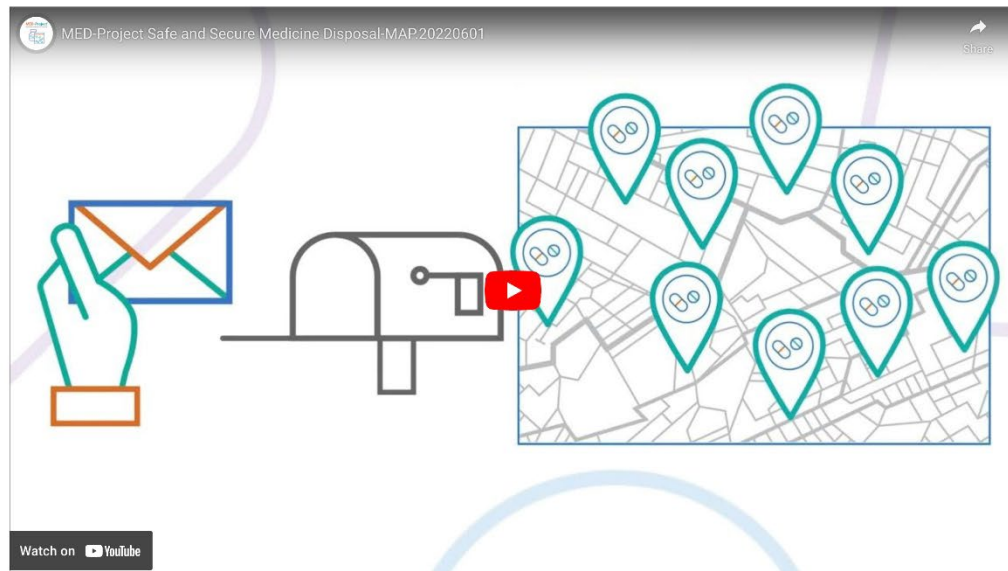
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Learn



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.



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Contact



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 [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: compliance@med-project.org

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.



Medicine Usage



Safe Storage Information



Find a Location



Mail-Back Services

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Frequently Asked Questions



- [What is MED-Project?](#) ▼
- [What should I do if I am having a medical emergency?](#) ▼
- [What should I do if I think I have ingested something poisonous?](#) ▼
- [What should I do if my pet has ingested medication?](#) ▼
- [Whom should I call with a question about my medication?](#) ▼
- [Where can I find information about the safe storage of medication?](#) ▼
- [How do I dispose of my expired or unwanted medicine?](#) ▼
- [Should I remove my personal information before disposing of my medication?](#) ▼
- [Where are the MED-Project disposal locations nearest me?](#) ▼
- [Will it cost me anything to dispose of my expired or unwanted medications?](#) ▼
- [Can I flush my medication down the toilet?](#) ▼
- [I am unable to go to a kiosk or attend a take-back event. How can I dispose of my expired or unwanted medicine?](#) ▼
- [I have a question not answered by this website. Is there someone I can contact with a question about MED-Project?](#) ▼
- [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 medicine in San Mateo County?](#) ▼
- [Where can I find information about California's Prop 65?](#) ▼



Medicine Usage



Safe Storage Information



Find a Location



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