

A Product Stewardship Plan For Unwanted Medicine from Households

City and County of San Francisco, California May 31, 2018

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I. Introduction

MED-Project LLC ("MED-Project"), on behalf of the participating companies identified in <u>Appendix A</u> submits this Product Stewardship Plan ("Plan") for Unwanted Medicine in compliance with the San Francisco Safe Drug Disposal Stewardship Ordinance, San Francisco Environment Code, Chapter 22, Division 1, Sections 2200-2219 ("Ordinance") and the San Francisco Department of the Environment ("Department") Regulation # SFE-16-01-SDDSO ("Regulation"). 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 Francisco Residents.

II. Contact Information

The primary contact person for MED-Project is:

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

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-PROJ or 1-844-633-7765.

Carrier is United Parcel Service, Inc. ("UPS"), the common carrier used by Vendor to transport Unwanted Medicine from Kiosk Drop-Off Sites and/or Take-Back Events.

County means the city and county of San Francisco, California.

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.

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 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, which will provide MED-Project Standard Mail-Back Packages to Residents.

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

Maintenance Technicians are service personnel who are trained to provide services related to kiosks that are part of the Program. This includes, but is not limited to, responding to damaged kiosks.

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

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

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

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

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

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

Service Convenience Goals are the goals established in Ordinance § 2205(b)(1).

Service Technicians are personnel trained to service Program kiosks.

Shipper is United States Postal Service ("USPS"), the shipper used by Vendor for the transport of Unwanted Medicine collected from Residents via Mail-Back Services.

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 § 2202 that qualify as "Unwanted Covered Drugs" under Ordinance § 2202. According to the Ordinance, Covered Drugs means "a drug sold in any form and used by City Residents, including prescription, nonprescription, brand name and generic drugs." 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 takeback program as part of a FDA managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 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;
- 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 and/or Take-Back Events does not include inhalers, Pre-Filled Injector Products, or iodine-containing medications.

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

1. Outreach

Per Ordinance § 2203(e)(2), MED-Project initially notified 167 sites with a licensed pharmacy and 10 LEA locations in the County of the opportunity to participate as a Kiosk Drop-Off Site. MED-Project continues to periodically perform outreach via calls, emails, and site visits, with the goal of establishing Kiosk Drop-Off Sites distributed throughout the County. As part of this outreach, MED-Project asks if the sites are interested in participating in the Program, whether the sites currently host a kiosk or provide other services for the disposal of Unwanted Medicine, whether pharmacies are DEA registrants, and if the sites would like more information regarding the Program.

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 work to satisfy the Service Convenience Goals through signed agreements with Kiosk Drop-Off Site Hosts. MED-Project will satisfy the Service Convenience Goals in any supervisorial district in which signed agreements have not been attained for the minimum number of Kiosk Drop-Off Sites through Mail-Back Distribution Locations. Take-Back Events may also be conducted when Kiosk Drop-Off Sites and Mail-Back Distribution Locations are not sufficient to satisfy the Service Convenience Goals. *See* Section V for details on how MED-Project will satisfy the Service Convenience Goals.

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

3. Convenience

Per Ordinance § 2205(b)(1), MED-Project will strive to establish five (5) Kiosk Drop-Off Sites in each of the 11 Supervisorial Districts geographically distributed to provide reasonably convenient and equitable access for all Residents. In Supervisorial Districts where a sufficient number of Kiosk Drop-Off Sites cannot be established, Mail-Back Distribution Locations will be established and, where necessary, Take-Back Events will be conducted in order to supplement the disposal of Unwanted Medicine by Residents in those areas.

Standard Mail-Back Services shall be available upon request for disabled and home-bound Residents, thereby offering more opportunities to dispose of Unwanted Medicine.

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

4. Services

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

The Plan will be implemented in a flexible manner, offering coverage to Residents through a combination of Kiosk Drop-Off Sites, Mail-Back Distribution Locations, and/or Take-Back Events, as needed. Over the course of implementation, additional Kiosk Drop-Off Sites will be established to the extent that (1) additional eligible LEAs and/or DEA-registered collector pharmacies agree to participate, and (2) contracts can be executed with such entities. MED-Project will establish Mail-Back Distribution Locations and/or Take-Back Events for underserved areas. For every engagement with LEAs and pharmacies, including the establishment of Kiosk Drop-Off Sites and/or the 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 schedules Take-Back Events.

Mail-Back Distribution Locations and/or Take-Back Events shall supplement Kiosk Drop-Off Sites in Supervisorial Districts where the Service Convenience Goals are not met through signed agreements with Kiosk Drop-Off Site Hosts. As MED-Project obtains additional agreements with Kiosk Drop-Off Site Hosts, these supplemental services will decrease.

For more information regarding Take-Back Event scheduling, coverage, and frequency, *see* Section V.C.

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

Although Kiosk Drop-Off Sites will not provide kiosk collection for Pre-filled Injector Products, inhalers, and iodine-containing medications, Mail-Back Services for Pre-filled Injector Products, inhalers, and iodine-containing medications will be available through the Call Center and MED-Project Website for all Residents. Under a current DEA General Public Fact Sheet dated October 21, 2016 (the "General Public Fact Sheet"), DEA suggests that Residents should not dispose of asthma inhalers or iodine-containing medications in collection receptacles or mail-back packages containing controlled substances. If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).

MED-Project will inform the Department of changes to Kiosk Drop-Off Sites, Take-Back Events, and/or Mail-Back Distribution Locations and Program services according to Ordinance § 2212.

B. Kiosk Drop-Off Sites

Kiosk Drop-Off Sites will be strategically placed across the County in order to best meet the Service Convenience Goals established by the Ordinance. This network will provide Residents a number of different outlets to participate in the Program. All Kiosk Drop-Off Sites shall provide Residents with access to Program kiosks during regular business hours.

1. Kiosk Drop-Off Site Locations

MED-Project initially contacted 10 LEAs and 167 sites with a licensed pharmacy located in the County about the opportunity serve as a Kiosk Drop-Off Site. MED-Project outreach to sites began with a letter to potential collection sites in January 2016, informing the sites of the upcoming Program, followed by calls, emails, and faxes to sites that did not respond to the letter. Upon receipt of the Notice of Determination issued in July 2016 from the County, MED-Project performed additional outreach in August 2016 using a combination of letters, faxes, emails and phone calls to potential sites. Potential sites were separated into LEA, independent pharmacy, hospitals/clinics with an

onsite pharmacy, and chain pharmacy categories. Chain pharmacies and health systems were approached at the headquarters level based upon the presence of sites across multiple jurisdictions.

All independent pharmacies and LEAs had multiple methods of contact in August 2016. This phase of the outreach campaign sought to familiarize sites with the Program and MED-Project, followed by phone calls and emails focused on recruiting interested sites and distributing agreements. Inperson site visits began in September 2016 once specific points of contact at potential sites were determined. Where possible, MED-Project partnered with the County to educate and encourage potential sites to participate.

Of the locations contacted, all LEAs and 101 pharmacies expressed interest in participating in the Program. Kiosk Drop-Off Sites and Mail-Back Distribution Locations that are currently participating in the Program are identified in <u>Appendix C</u>. MED-Project will continue outreach to potential Kiosk Drop-Off Sites that are not participating in the Program according to Ordinance Section 2203(e)(2), such as sites listed in <u>Appendix D</u> via emails, phone calls and in-person site visits on a frequent basis, while balancing the needs to meet the Service Convenience Requirement with outreach fatigue on the part of potential sites. Additionally, annual notification letters are sent to nonparticipating or new Retail Pharmacies.

MED-Project will establish Mail-Back Distribution Locations, and/or schedule Take-Back Events in any Supervisorial District where there are fewer than five (5) Kiosk Drop-Off Sites. *See* Section V.C for more information on Take-Back Events and Section V.E for Mail-Back Services.

As required under Ordinance § 2205(b)(4), the Plan will include as a Kiosk Drop-Off Site any eligible retail pharmacy or LEA willing to serve voluntarily as a Kiosk Drop-Off Site for Unwanted Medicine and able to meet all applicable laws, regulations, and other legal requirements within three months of their offer to participate.

2. Drop-Off Site Kiosk Placement and Maintenance Program

Kiosk installation shall take place within 90 days of a signed agreement and shall be the responsibility of MED-Project at LEAs and pharmacy Kiosk Drop-Off Sites when the Kiosk Drop-Off Site Host has identified a compliant placement location. All kiosks in the Program must be securely placed and maintained inside a collector's registered location or LEA's physical location in accordance with DEA Rule §§ 1317.75(d)(1) and 1317.35(a). At pharmacies, kiosks will be placed in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (i.e., can be seen from the counter), pursuant to § 1317.75(d)(2). At a hospital or clinic with an on-site pharmacy, kiosks will be placed in an area regularly monitored by employees but not near areas of the facility where urgent or emergency care is provided. § 1317.75(d)(2)(i). Kiosk placement will also comply with any applicable Board of Pharmacy requirements. Costs associated with installation and maintenance will be paid by MED-Project per the contracts with the Kiosk Drop-Off Site Hosts.

The maintenance program will address items such as:

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

3. Kiosk Specifications

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

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

The proposed design of the pharmacy kiosk and proposed signage (<u>Appendix E</u>) satisfies these requirements through the use of heavy gauge steel; multiple locking mechanisms, including a locking mechanism on the drop-slot; a tamper-proof slot; and commercial hinges.³ The design will increase the likelihood of consumer participation by providing easy access to wheelchair users. The locking mechanism on the drop-slot will prevent kiosk overflow once the container has reached its maximum level and is locked by the Kiosk Drop-Off Site Host. MED-Project pharmacy kiosks will come with appropriate regulatory signage and instructions, including an instruction to remove personal information from any Unwanted Medicine and packaging before depositing them and language required under the DEA Rule⁴ and by the Board of Pharmacy. Kiosk signage will provide information about what is and is not accepted in the kiosk.

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

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

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

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

4. Kiosk Collection

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

Section 1317.75(c) prohibits the counting, sorting, inventorying, or individual handling of any substances deposited into a pharmacy kiosk. Additionally, § 1317.60 limits inner liner access to

³ As discussed in Section XI, if applicable, MED-Project will coordinate with other approved product stewardship plans to develop clear standardized instructions for Residents to use kiosks and a consistent design. <u>Appendix E</u> provides the kiosk design and signage MED-Project expects to propose when coordinating with other approved product stewardship plans.

⁴ 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."

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

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

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

Pharmacy kiosks will be located where an employee is present affording employees the opportunity to visually inspect Unwanted Medicine Residents attempt to deposit. *See* Section V.B.2. LEA kiosks will be located inside the LEA's physical location. *See* Section V.B.2. MED-Project's Kiosk Drop-Off Site collection system will also comply with all applicable Board of Pharmacy requirements.

Pick-up of Unwanted Medicine collected at Kiosk Drop-Off Sites will be scheduled for all Kiosk Drop-Off Sites, year-round, based on their regular business hours and volume collected. When arriving at a Kiosk Drop-Off Site, the kiosk will be checked by the Service Technicians for any damage.

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

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

A review of 2017 calendar year data from MED-Project Kiosk Drop-Off Sites indicated the average time for UPS pick-ups was approximately 2 to 3 days, with no pick-ups exceeding 14-days, after the Service Technician packaged the sealed inner liner for transport. MED-Project will meet with Vendor on a regular basis to monitor service metrics, including pick-up timing. Vendor will prepare the materials for shipment and perform applicable pre-transportation functions to comply with DOT Hazardous Materials Regulations. All materials are tracked at pick-up and destruction using a unique identifier located on the inner liner. The weight of the inner liner is recorded upon receipt by Vendor at the facility identified in Section X.

5. Frequency of Pick-Up

Initially, all Kiosk Drop-Off Sites will be scheduled for a monthly pick-up from the kiosk. Vendor will communicate with MED-Project in the event that the frequency of pick-up needs to be changed based on the volumes collected over time. Vendor will monitor the volumes per service to ensure that all sites are receiving the appropriate service frequency. Vendor will manage pick-up services as frequently as necessary to prevent overflow of the kiosk without providing unnecessary interruption to the participating Kiosk Drop-Off Site. Moreover, Vendor will monitor the weight of Unwanted Medicine collected at each participating Kiosk Drop-Off Site.

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

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

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

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

7. Unplanned Event Preparedness

Vendor maintains a network of emergency responders that can be called on 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.

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 phone number and/or email address. Vendor is able to respond within two to three hours in most cases 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, personal items that a Resident deposits into the kiosk (i.e. dentistry, watch, keys, wallet, etc.) will not be retrieved.

C. Take-Back Events

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

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

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

1. Method

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

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

2. Procedures

MED-Project will partner with LEAs to ensure that at least one law enforcement officer oversees collection at all Take-Back Events 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 § 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 § § 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 via unique identifiers to a facility identified in Section X, where they shall be incinerated. Vendor will ship the containers (and inner liners) in accordance with the requirements outlined in Section XIV.B.

3. Fees and Costs

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

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

Vendor and Carrier shall manage the Unwanted Medicine from Kiosk Drop-Off Sites and Take-Back Events in compliance with all applicable laws, regulations, and other legal requirements. Carrier and/or Vendor shall deliver Unwanted Medicine collected from 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.

E. Mail-Back Services for Unwanted Medicine

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

- Standard Mail-Back Services for disabled and home-bound Residents as described in Section V.E.1;
- Standard Mail-Back Services for the collection of iodine-containing medications for all Residents as described in Section V.E.2;
- Injector Mail-Back Services for the collection of Pre-filled Injector Products for all Residents as described in Section V.E.3; and
- Inhaler Mail-Back Services for the collection of inhalers for all Residents as described in Section V.E.4.

If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).

1. Standard Mail-Back Services

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

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

- Nondescript and without any markings or information potentially indicating that they contain Unwanted Medicine, including controlled substances;
- Water and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with and delivered to the 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 the 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 § 1317.70(d). As required under § 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 § 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 § 1317.70(f). Vendor will keep all records required under the DEA Rule, including those identified in § 1304.22(f).

2. Standard Mail-Back Services for Iodine-Containing Medications

For iodine-containing medications, MED-Project will offer all Residents Standard Mail-Back Services and Standard Mail-Back Packages, via the Call Center and/or MED-Project Website. Residents are instructed not to commingle iodine-containing medications with controlled substances. The prepaid shipping label will direct the Standard Mail-Back Package to the facility identified in Section X. If the General Public Fact Sheet is modified to allow for commingling of iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).

See Appendix G for a sample package and package specifications.

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

For Pre-filled Injector Products, MED-Project will offer all Residents Injector Mail-Back Services and Injector Mail-Back Packages, via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Injector Mail-Back Package to the facility identified in Section X. An instruction sheet describing how to properly dispose of Pre-filled Injector Products that 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 will be included with the Injector Mail-Back Package.

See Appendix H for a sample package and package specifications.

4. Inhaler Mail-Back Services for Inhalers

For inhalers, MED-Project will offer all Residents Inhaler Mail-Back Services and Inhaler Mail-Back Packages, via the Call Center and/or MED-Project Website. The pre-paid shipping label will direct the Inhaler Mail-Back Packages to the facility identified in Section X. An instruction sheet will be included with the Inhaler Mail-Back Package that describes how to properly dispose of inhalers,

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 controlled substances. If the General Public Fact Sheet is modified to allow for commingling inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers (except for certain services required pursuant to Ordinance § 2205(b)(5)).

See Appendix I for sample package specifications.

5. Mail-Back Package Availability

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

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

Standard Mail-Back Services for iodine-containing medications, Injector Mail-Back Services for Prefilled Injector Products, and Inhaler Mail-Back Services for inhalers, will be available to all Residents through the Call Center and MED-Project Website. As noted above, if the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).

All Mail-Back Services will supply packages that contain an insert with instructions for use and information about other options for disposing of Unwanted Medicine in the Required Languages.

6. Mail-Back Package Collection and Disposal

The following general procedures will be applied to the request and processing of mail-back packages:

- 1. Requests by Residents made via Call Center/Website and are verified, and logged;
- 2. Reguests 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 origin, type, and average weight of mail-back packages.

Residents will be directed to follow the instructions provided via Mail-Back Services. The USPS estimates up to three business days for delivery of First Class Mail. Mail-Back Services shall direct packages to an approved facility in accordance with their contents and packages will be handled in compliance with all applicable laws.

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

Injector Mail-Back Packages will be tracked using a unique identifier to a disposal facility for incineration. *See* the facilities identified in Section X. MED-Project's request for approval to incinerate Injector Mail-Back Packages at a municipal solid waste combustor and medical waste incinerator is included in Appendix K.

Inhaler Mail-Back Packages containing inhalers will be tracked using a unique identifier to a disposal facility for incineration. *See* the facilities identified in Section X. MED-Project's request for approval to incinerate Inhaler Mail-Back Packages containing inhalers at a municipal solid waste combustor and medical waste incinerator is included in Appendix L.

VI. Plan and Collection Goals

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

MED-Project anticipates that, once all Kiosk Drop-Off Sites are fully operational, the Program will collect approximately 360 pounds per Kiosk Drop-Off Site during the calendar year. Assuming 55 Kiosk Drop-Off Sites are operational for the full year, MED-Project anticipates collecting approximately 19,800 pounds of Unwanted Medicine from Kiosk Drop-Off Sites in 2019. *See* Section V.B for more information about Kiosk Drop-Off Site collection.

MED-Project anticipates a continued need in 2018 to supplement Kiosk Drop-Off Sites in a few Supervisorial Districts through Mail-Back Distribution Locations and/or Take-Back Events. Based on Take-Back Event collection totals in 2017, MED-Project anticipates collection of approximately 50 pounds of Unwanted Medicine per Take-Back Event.

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

Goal Area	Short-Term	Long-Term
Collection	Within 90 days of Plan approval, implement Mail-Back Services for inhalers, iodine-containing medications, and Pre-filled Injector Products via the MED-Project Website and Call Center. Continue to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites, Mail-Back Distribution Locations, and/or Take-Back Events.	Increase retail chain pharmacy participation to satisfy the Service Convenience Goals through established Kiosk Drop-Off Sites in a minimum of seven (7) out of eleven (11) Supervisorial Districts. Eliminate Take-Back Events through the establishing of Kiosk Drop-Off Sites and Mail-Back Distribution Locations. Reduce the number of Mail-Back Distribution Locations. If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for inhalers and/or iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).
Education & Public Outreach	Develop baseline number of MED-Project Website page views or unique visitors. Establish a baseline of LEAs; retail pharmacies; other pharmacies (healthcare, etc.); community groups; and other third parties contacted, and report appropriate statistics as outlined in the Survey and Annual Report Sections of this Plan. Establish a baseline number of media outlets receiving press advisory, with a minimum of five outlets. Establish a baseline percentage of community centers reached. Establish a baseline number of messages returned by MED-Project within predetermined timeframe.	On an ongoing basis, MED-Project may revise and/or add communications materials based on changes to the Plan. MED-Project will evaluate media and public outreach as well as collect feedback by survey in order to make adjustments and improvements to the Program. The review will measure percent awareness of the Program, assess to what extent Kiosk Drop-Off Sites and other collection methods are convenient and easy to use, and assess knowledge and attitudes about risks of abuse, poisonings and overdoses from prescription and nonprescription medicines used in the home. Results of the review will be published on the MED-Project Website established under Section XI.D.2.
Collector Outreach	Outreach to all potential eligible Kiosk Drop-Off Site Hosts according to requirements as outlined in Ordinance Section 2203(e)(2).	Ongoing communication with pharmacies and LEAs. Evaluation of Kiosk Drop-Off Sites against the Service Convenience Goals.

VII. Patient Privacy

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

In addition to kiosk signage, 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 will be opaque rather than clear. In addition, inner liners used at Kiosk Drop-Off Sites and Take-Back Events will be opaque rather than clear, in compliance with the DEA Rule. This will prevent anyone, including the Service Technician, from seeing any information on the containers placed in the kiosks.

Materials to help Residents cross out any personally identifiable information will also be available at Take-Back Events. This will ensure any patient information on drug packaging will be unreadable.

VIII. Call Center

Per Ordinance § 2206, MED-Project will operate a Call Center jointly with all other approved stewardship programs operating in the County. Questions from Residents will be managed through an interactive voice response ("IVR") system and with the support of an operator available during business hours. If the operator is unavailable, a Resident will be able to leave a message to which the operator will respond within one business day. All operators are trained to respond based on the requirements set by MED-Project. When calling the Call Center, the caller will enter information to verify their residency in the County, and then will be directed to a menu to select their language of choice as English, Spanish, Chinese Russian or Tagalog, to continue.

The IVR will answer general questions, including questions on the following topics:

- 1. Items that can be disposed of;
- 2. Disposal options;
- 3. Directions to the MED-Project Website for additional information; and
- 4. Information about available Mail-Back Services.

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

IX. Training

Operational procedures, including training, are the responsibility of the Kiosk Drop-Off Site Host. MED-Project will support training if agreed to with the Kiosk Drop-Off Site Host.

Training support may include:

- Information regarding modification of DEA registrant status to collector for pharmacies;
- Information regarding California Board of Pharmacy regulations and requirements for pharmacies;
- Information about kiosk functionality;
- Materials describing items that are accepted and not accepted in kiosks and mail-back packages;
- Help Desk information for Kiosk Drop-Off Sites with questions or requests for support; and
- Call Center and MED-Project Website information for Residents.

Additionally, MED-Project will manage a support hotline to answer questions and monitor comments for participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations.

The support hotline will support two general communication functions:

- 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.

All messages will be checked during business hours of 9 AM to 5 PM PST, Monday through Friday. Each inquiry will be addressed and prioritized based on the urgency of the issue. Messages received 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's internal training process will address the following:

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

A. Service Technician Training

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

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

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

X. Vendor, Transporter, and Disposal Facility Information

Kiosk and Take-Back Event Collection Services

A. Vendor for Kiosk Drop-Off Sites and/or Take-Back Events

- Name: Stericycle Specialty Waste Solutions, Inc. will service Kiosk Drop-Off Sites and Take-Back Events. Stericycle Specialty Waste Solutions, Inc. may also be used to transport Unwanted Medicine from Take-Back Events to Clean Harbors-Aragonite or Veolia-Port Arthur. Stericycle Specialty Waste Solutions, Inc. may also be used to transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Veolia-Port Arthur.
- Address: 2850 100th Court NE Blaine, MN 55449
- Phone: 612-285-9865
- Website: www.stericycleenvironmental.com

B. Carrier for Kiosk Drop-Off Sites and/or Take-Back Events

- Name: United Parcel Service, Inc. will transport Unwanted Medicine from Kiosk Drop-Off Sites to the Stericycle, Inc., Indianapolis, Indiana Facility. United Parcel Service, Inc. may also be used to transport Unwanted Medicine from Take-Back Events to the Stericycle, Inc., Indianapolis, Indiana Facility.
- Address: 55 Glenlake Parkway NE, Atlanta, GA, 30328
- Phone: 800-PICK-UPS
 Wobsite: www.LIPS cor
- Website: <u>www.UPS.com/</u>

C. Reverse Distributor Facility & Transporter for Kiosk Drop-Off Sites and/or Take-Back Events

1. Reverse Distributor Facility

- Name: **Stericycle, Inc., Indianapolis, Indiana Facility** will receive Unwanted Medicine from Carrier.
- Address: 2670 Executive Drive, Suite A, Indianapolis, IN 46241-9901
- Phone: 317-275-7530
- Website: <u>www.stericycleenvironmental.com</u>

 Type: DEA Registered Collector and Reverse Distributor & Permitted Hazardous Waste (RCRA) Treatment, Storage, and/or Disposal Facility

2. Transporter

• Name: **Heritage Transport** will transport Unwanted Medicine from the Stericycle, Inc., Indianapolis, Indiana Facility to Heritage Thermal Services – Ohio.

Address: 1626 Research Way, Indianapolis, IN 46231

• Phone: 317-486-2973

Website: http://www.heritage-enviro.com/

D. Disposal Facility for Kiosk Drop-Off Sites and/or Take-Back Events

1. Disposal Facility

 Name: Heritage Thermal Services – Ohio will incinerate Unwanted Medicine received from the Stericycle, Inc., Indianapolis, Indiana Facility by Heritage Transport.

• Address: 1250 Saint George Street, East Liverpool, Ohio, 43920

Phone: 800-545-7655

Website: http://www.heritage-thermal.com/
 Type: Permitted Hazardous Waste Incinerator

2. Direct Transport Disposal Facility

 Name: Clean Harbors - Aragonite will incinerate Unwanted Medicine collected at Take-Back Events that is transported by Stericycle Specialty Waste Solutions, Inc.

• Addresses: 3 Miles E 7 Miles N of Knolls, Wendover, UT 84083

• Phone: 435-884-8900

• Website: www.cleanharbors.com

• Type: Permitted Hazardous Waste Incinerator

3. Secondary Disposal Facility

• Name: **Veolia** – **Port Arthur** will incinerate Unwanted Medicine that cannot be processed by Heritage Thermal Services - Ohio and/or Clean Harbors - Aragonite.

• Addresses: 7665 Texas Highway 73, Beaumont, TX 77705.

Phone: 409-736-2821

• Website: www.veiolianorthamerica.com

• Type: Permitted Hazardous Waste Incinerator

Standard Mail-Back Services

E. Vendor for Standard Mail-Back Packages

 Name: Stericycle Specialty Waste Solutions, Inc. will provide Standard Mail-Back Packages.

• Address: 2850 100th Court NE Blaine, MN 55449

• Phone: 612-285-9865

• Website: www.stericycleenvironmental.com

F. Shipper of Standard Mail-Back Packages

 Name: United States Postal Service will ship Standard Mail-Back Packages to the Stericycle, Inc., Indianapolis, Indiana Facility and the Stericycle, Inc. Warren, Ohio Facility.

• Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260

Phone: 202-268-2000Website: www.USPS.com/

G. Disposal Facilities for Standard Mail-Back Packages

1. Disposal Facility

- Stericycle, Inc., Warren, Ohio Facility will incinerate the Standard Mail-Back Packages received from the United States Postal Services and certain forwarded packages via United Parcel Service, Inc. See 21 C.F.R. § 1317.70(e).
- Address: 1901 Pine Ave SE, Warren, Ohio 44483
- Phone: 330-393-0370
- Website: www.stericycleenvironmental.com
- Type: DEA Registered Collector and Reverse Distributor & Medical Waste Incinerator

Injector Mail-Back Services

H. Vendor for Injector Mail-Back Packages

- Name: PureWay Compliance Inc. will provide Injector Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy TX 77450
- Phone: 877-765-3030
- Website: http://pureway.com/

I. Shipper of Injector Mail-Back Packages

- Name: United States Postal Service will transport Injector Mail-Back Packages to Daniels Sharpsmart, Inc..
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: 202-268-2000
- Website: www.USPS.com/

J. Transfer Facility for Injector Mail-Back Packages

- Name: Daniels Sharpsmart, Inc. will be utilized to receive Injector Mail-Back Packages and provide for transport to the disposal facility.
- Address: 4144 East Therese Avenue, Fresno, CA 93725
- Phone: 559-834-6252
- Website: http://danielsinternational.com/
- Type: Medical Waste Treatment Facility

K. Transporter(s) for Injector Mail-Back Packages

1. Transporter 1

- Name: Lula Logistics Inc. will transport Injector Mail-Back Packages received from Daniels Sharpsmart, Inc. to the disposal facility.
- Address: 8268 Nelson Ridge Ln, Las Vegas, NV 89178
- Phone: 352-346-6219
- email: <u>lulalogistics@yahoo.com</u>
- Type: Contract Carrier

2. Transporter 2

- Name: GPB Logistics Inc. will transport Injector Mail-Back Packages received from Daniels Sharpsmart, Inc. to the disposal facility.
- Address: 2115 W Farwell Ave #103, Chicago, IL 60645
- Phone: 773-968-7210
- Website: www.gpblogistics.com
- Type: Contract Carrier

L. Disposal Facilities for Injector Mail-Back Packages

1. Disposal Facility 1

- Name: **Covanta Huntsville, Inc.** will incinerate Injector Mail-Back Packages received from Daniels Sharpsmart, Inc.
- Address: 5251 Triana Blvd SW, Huntsville, AL 35805
- Phone: 256-882-1019
- Website: https://www.covanta.com/Our-Facilities/Covanta-Huntsville
- Type: Municipal Waste Combustor

2. Disposal Facility 2

- Name: **Covanta Marion, Inc.** will incinerate Injector Mail-Back Packages received from Daniels Sharpsmart, Inc.
- Address: 4850 Brook Lake Rd. NE, Brooks, OR 97305
- Phone: 503-393-0890
- Website: http://www.covanta.com/facilities/facility-by-location/marion.aspx
- Type: Municipal Waste Combustor

3. Disposal Facility 3

- Name: Healthcare Environmental Services, Inc. (HESI) will incinerate Injector Mail-Back Packages received from Daniels Sharpsmart, Inc.
- Address: 1420 40th St. N, Fargo, ND 58102
- Phone: 701-282-7373
- Website: <u>www.HESIservices.com</u>Type: Medical Waste Incinerator

Inhaler Mail-Back Services

M. Vendor for Inhaler Mail-Back Packages

- Name: PureWay Compliance Inc. will provide Inhaler Mail-Back Packages.
- Address: 20501 Katy Freeway, Suite 206, Katy, TX 77450
- Phone: 877-765-3030
- Website: http://pureway.com/

N. Shipper of Inhaler Mail-Back Packages

- Name: United States Postal Service will transport Inhaler Mail-Back Packages to Daniels Sharpsmart, Inc.
- Address: 475 L'Enfant Plaza, S.W. Washington, DC 20260
- Phone: 202-268-2000Website: www.USPS.com/

O. Transfer Station for Inhaler Mail-Back Packages

- Name: **Daniels Sharpsmart, Inc.** will be utilized to receive Inhaler Mail-Back Packages and provide for transport to the disposal facility.
- Address: 4144 East Therese Avenue, Fresno, CA 93725
- Phone: 559-834-6252
- Website: http://danielsinternational.com/
- Type: Medical Waste Treatment Facility

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

1. Transporter 1

 Name: Lula Logistics Inc. will transport Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc. to the disposal facility.

• Address: 8268 Nelson Ridge Ln, Las Vegas, NV 89178

• Phone: 352-346-6219

• email: <u>lulalogistics@yahoo.com</u>

Type: Contract Carrier

2. Transporter 2

• Name: **GPB Logistics Inc.** will transport Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc. to the disposal facility.

Address: 2115 W Farwell Ave #103, Chicago, IL 60645

• Phone: 773-968-7210

• Website: www.gpblogistics.com

• Type: Contract Carrier

Q. Disposal Facilities for Inhaler Mail-Back Packages

1. Disposal Facility 1

• Name: **Covanta Huntsville, Inc.** will incinerate Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.

Address: 5251 Triana Blvd SW, Huntsville, AL 35805

• Phone: 256-882-1019

• Website: https://www.covanta.com/Our-Facilities/Covanta-Huntsville

• Type: Municipal Waste Combustor

2. Disposal Facility 2

• Name: **Covanta Marion, Inc.** will incinerate Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.

Address: 4850 Brook Lake Rd. NE, Brooks, OR 97305

• Phone: 503-393-0890

• Website: http://www.covanta.com/facilities/facility-by-location/marion.aspx

• Type: Municipal Waste Combustor

3. Disposal Facility 3

• Name: **Healthcare Environmental Services, Inc. (HESI)** will incinerate Inhaler Mail-Back Packages received from Daniels Sharpsmart, Inc.

Address: 1420 40th St. N, Fargo, ND 58102

Phone.: 701-282-7373

Website: <u>www.HESIservices.com</u>Type: Medical Waste Incinerator

XI. Unwanted Medicine Educational and Outreach Programming

A. Overview

Per Ordinance Section 2206(a) and the Regulation, MED-Project will perform public education and outreach to educate Residents about the collection and disposal of Unwanted Medicine from households.

B. Audiences

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

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

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

Demographic information, including race, ethnicity, language, age, and geographic data, may be analyzed in order to appropriately direct outreach and create educational materials to best serve the unique needs of identified demographics.

C. Messages

MED-Project anticipates that messaging will:

- Educate Residents about the appropriate use, storage, and disposal of Unwanted Medicine;
- Educate Residents about available Mail-Back Services; and
- Provide Residents with information about available locations and events in their area that offer disposal of Unwanted Medicine.

Key points of emphasis might include:

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

D. Tools/Communications Channels

The Program will include a number of components designed to reach consumers and provide consistent access to timely and relevant information. Distribution of materials will likely include audiences such as LEAs, pharmacies, health care providers and systems, health associations, local government agencies, and other community organizations. MED-Project expects that the tools and communication channels will include:

1. Phone

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

- IVR support in the Required Languages. The Call Center will also provide an option for callers to be transferred to an operator.
- Basic information about the Program, such as where to obtain more information (e.g., the MED-Project Website), and an option to talk with an operator to find Kiosk Drop-Off Sites, Mail-Back Distribution Locations, and/or Take-Back Events, if applicable, in the Resident's zip code or local area.
- A recorded call script directing callers with medical emergencies to call 911 and directing Residents with medication-related questions to contact their health care provider(s).

Please see Appendix M for a sample call script.

2. MED-Project Website

MED-Project will develop a mobile-friendly MED-Project Website with translations in the Required Languages. MED-Project expects information available to users will include pages to help Residents find locations of Kiosk Drop-Off Sites and Mail-Back Distribution Locations, as well as educational materials, frequently asked questions and responses, Take-Back Event dates and locations, if applicable, and results of the most recent survey of Program awareness.

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

3. Materials

Educational materials about the Program and how to properly dispose of Unwanted Medicine, Prefilled Injector Products, inhalers and iodine-containing medications will be available through the MED-Project Website, through potential third-party partners, community organizations, and at Kiosk Drop-Off Sites. Educational materials will also communicate that, in accordance with the Regulation, the disposal of Unwanted Medicine in any refuse collection container, including a collection cart, receptacle, bin, or debris box, is discouraged.

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

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

4. Media Outreach

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

- See Appendix M for a sample call script with the toolkit including flyers in Appendix O and the sample MED-Project Website information included in Appendix N.
- See Appendix F for a sample list of key media outlets.
- See Appendix P for a sample list of social media outlets
- MED-Project expects to achieve the required combined target reach percent of 50% at a 2+ frequency for the duration of one month, at least three times per year for years 2 through 4 of the Program. MED-Project intends to meet these requirements with a combination of digital media campaigns, print ads, and traditional broadcast media. The quantity and frequency will be confirmed as activities are completed.
- MED-Project will adjust accordingly to meet specific targets set for every fifth year
 of the Program in Regulation § 1.5. The quantity and frequency will be confirmed as
 activities are completed.

E. Collaboration with County Officials and Community Organizations

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

The Program will perform the following activities:

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

F. Disclaimer

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

XII. Survey

MED-Project will coordinate with other approved stewardship plans, if applicable, to conduct two biennial surveys; one for Residents and another for pharmacists, veterinarians, and/or health care professionals who interact with members of the community, according to requirements in the Ordinance and Regulation.

Survey questions will be designed to measure, at a minimum, (1) percent awareness of the Programs, (2) whether drop-off sites and other collection methods are convenient and easy to use, and (3) knowledge and attitudes about risks of abuse, poisonings, and overdoses from prescription and nonprescription drugs used in the home. As required by the Ordinance § 2206(a)(4), draft survey questions will be submitted to the Director for review and comment thirty (30) days prior to distribution. Results of the survey will be reported to the Director and made public on the MED-Project Website described under Section XI.D.2. The privacy of all survey respondents will be maintained.

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

MED-Project will biennially adjust the level of future outreach activities to increase reach, frequency and duration until the awareness of at least 50% of the target audience is achieved, should the results of the prior biennial survey show that target audience awareness of the collection program is less than 50%.

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 § 2204(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 and Take-Back Events, including a waste stream for drug packaging and a waste stream for the drugs themselves.

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

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

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

MED-Project education and outreach materials instruct Residents to return Unwanted Medicine at a Kiosk Drop-Off Site, via Mail-Back Services, or at a Take-Back Event, 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 § 2204(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" (referred to herein as the "DEA Rule") 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)⁵; 1317.65(d) (Take-Back Events); 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 § 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 onsite 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 with on-site pharmacies;
- Provides for collection of controlled substances at Take-Back Events;
- Provides for the use of mail-back programs to collect controlled substances;
- Allows for the commingling of controlled and non-controlled substances;
- Establishes detailed collection, recordkeeping, security, and other measures for all approved collection methods; and
- Provides that all collected pharmaceutical products be destroyed so that the products are rendered non-retrievable.

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

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

⁵ 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." §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* §§ 1317.65(d); 1317.70(b).

the DEA Rule. See §§ 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 § 1301.13(j).

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

B. United States Department of Transportation (DOT)

When transporting Unwanted Medicine, Vendor will ensure compliance with the DOT Hazardous Materials Regulations (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. 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 Report⁶

An annual report will be provided to the Director within six months after the end of the first twelvemonth period of operation and annually thereafter. Ordinance § 2209(a). This report will be provided in the format required by the Ordinance and Regulation.

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, Take-Back Events, 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 conducted;
- 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 including requirements as described in Regulation § D(2.0).
- A description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used;
- A summary of the Plan's 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 Plan's total expenditures.

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⁶ The first annual report reporting period included services from October 25, 2016 through December 31, 2017. Annual reports thereafter have a reporting period including services for the prior calendar year.

Appendix A

MED-Project Participants

The list of participating Producers in MED-Project's Program in the County is provided to the County every 60 days to satisfy Ordinance requirements. The list of participating Producers as of April 13, 2018, is provided below.

Parent Company	Company Name	Address	City	ST	Zip	Country
3M Corporation	3M Drug Delivery Systems	3M Center 275- 5W-06	Saint Paul	MN	55144	United States
3M Corporation	3M Critical and Chronic Care	3M Center 275- 5W-06	Saint Paul	MN	55144	United States
3M Corporation	3M Drug Delivery Systems	3M Center	St. Paul	MN	55144	United States
3M Corporation	3M Infection Prevention	3M Center	St. Paul	MN	55144	United States
3M Corporation	3M Oral Care	3M Center	St. Paul	MN	55144	United States
AbbVie Inc.	AbbVie Inc.	1 North Waukegan Road	North Chicago	IL	60064	United States
AbbVie Inc.	Pharmacyclics, subsidiary of AbbVie Inc.	999 East Arques Avenue	Sunnyvale	CA	94085	United States
ACADIA Pharmaceuticals Inc.	ACADIA Pharmaceuticals Inc.	3611 Valley Centre Drive, Suite 300	San Diego	CA	92130	United States
Accord Healthcare Inc.	Accord Healthcare Inc.	1009 Slater Road	Durham	NC	27703	United States
Acorda Therapeutics, Inc.	Acorda Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
Acorda Therapeutics, Inc.	Acorda Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
Acorda Therapeutics, Inc.	Civitas Therapeutics, Inc.	420 Saw Mill River Road	Ardsley	NY	10502	United States
Actelion Pharmaceuticals US, Inc.	Actelion Pharmaceuticals US, Inc.	5000 Shoreline Court, Suite 200	South San Francisco	CA	94080	United States
Actelion Pharmaceuticals US, Inc.	Ceptaris Therapeutics, LLC	5000 Shoreline Court Suite 200	South San Francisco	CA	94080	United States
Actelion Pharmaceuticals US, Inc.	CoTherix, Inc.	5000 Shoreline Court Suite 200	South San Francisco	CA	94080	United States
Aegerion Pharmaceuticals, Inc.	Aegerion Pharmaceuticals, Inc.	One Main Street	Cambridge	MA	02142	United States
Afaxys Inc.	Afaxys Inc.	PO Box 20639	Charleston	SC	29413	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Afaxys Inc.	Afaxys Pharmaceuticals (a division of Afaxys Inc.)	PO Box 20639	Charleston	SC	29413	United States
Akorn, Inc.	Akorn, Inc.	1925 West Field Court	Lake Forest	IL	60045	United States
Akorn, Inc.	Advanced Vision Research Inc. d.b.a. Akorn Consumer Health	C/O Akorn, Inc.	Lake Forest	IL	60045	United States
Akorn, Inc.	Akorn Animal Health, Inc.	C/O Akorn, Inc	Lake Forest	IL	60045	United States
Akorn, Inc.	Clover Pharmaceuticals Corp.	C/O Akorn, Inc.	Lake Forest	IL	60045	United States
Akorn, Inc.	Hi-Tech Pharmacal Co., Inc.	369 Bayview Avenue	Amityville	NY	11701	United States
Akorn, Inc.	Oak Pharmaceuticals, Inc.	C/O Akorn, Inc.	Lake Forest	IL	60045	United States
Akorn, Inc.	Olta Pharmaceuticals Corp.	C/O Akorn, Inc.	Lake Forest	IL	60045	United States
Akorn, Inc.	Versapharm, Incorporated	C/O Akorn, Inc.	Lake Forest	IL	60045	United States
Akrimax Pharmaceuticals, LLC	Akrimax Pharmaceuticals, LLC	11 Commerce Drive	Cranford	NJ	07016	United States
AKRON COATING & ADHESIVES	AKRON COATING & ADHESIVES	367 Stanton Ave	Akron	ОН	44301- 1468	United States
Alembic Pharmaceuticals Inc.	Alembic Pharmaceuticals	750 Highway 202	Bridgewater	NJ	08807	United States
Allergan, Inc.	Allergan, Inc.	2525 Dupont Dr	Irvine	CA	92612- 1599	United States
Allergan, Inc.	Actavis Pharma, Inc. (only for labeler code 52544)	400 Interpace Pkwy Bldg A	Parsippany	NJ	07054	United States
Allergan, Inc.	Allergan Sales, LLC	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Allergan USA, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Aptalis Pharma US, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Durata Therapeutics US Limited	c/o Durata Therapeautics, Inc.	Chicago	IL	60606	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Allergan, Inc.	Forest Laboratories, LLC (formerly Inc.)	Corporation Trust Centre	Wilmington New Castle	DE	19801	United States
Allergan, Inc.	Pacific Pharma, Inc.	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Warner Chilcott (US), LLC	5 Giralda Farms	Madison	NJ	07940- 1027	United States
Allergan, Inc.	Watson Laboratories, Inc. (only for labeler code 52544)	400 Interpace Pkwy Bldg A	Parsippany	NJ	07054	United States
Alva-Amco Pharmacal Companies, Inc.	Alva-Amco Pharmacal Companies, Inc.	7711 N Merrimac Avenue	Niles	IL	60714- 3423	United States
Alvogen Pharma US, Inc.	Alvogen Pharma US, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Almatica Pharma, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Alvogen, Inc.	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	County Line Pharmaceuticals LLC	10 Bloomfield Ave	Pine Brook	NJ	07058	United States
Alvogen Pharma US, Inc.	Norwich Pharmaceuticals, Inc.	6829 State Highway 12	Norwich	NY	13815	United States
AMAG Pharmaceuticals, Inc.	AMAG Pharmaceuticals, Inc.	1100 Winter Street	Waltham	MA	02451	United States
AMAG Pharmaceuticals, Inc.	AMAG Pharma USA, Inc.	1100 Winter Street	Waltham	MA	02451	United States
Amarin Pharma, Inc.	Amarin Pharma, Inc.	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Corp	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Corp. PLC	1430 Rt. 206	Bedminster	NJ	07921	United States
Amarin Pharma, Inc.	Amarin Pharmaceuticals Ireland Ltd.	1430 Route 206	Bedminster	NJ	07921	United States
Amerisource Health Services, LLC DBA: American Health Packaging	Amerisource Health Services, LLC DBA: American Health Packaging	2550-A John Glenn Avenue	Columbus	ОН	43217	United States
Amgen Inc.	Amgen Inc.	One Amgen Center Drive	Thousand Oaks	CA	91320	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Amgen Inc.	Amgen USA	One Amgen Center Drive	Thousand Oaks	CA	91320	United States
Amgen Inc.	Immunex Corporation	One Amgen Center Drive	Thousand Oaks	CA	91320	United States
Amgen Inc.	Onyx Pharmaceuticals	249 N. Grand Avenue	South San Francisco	CA	94080	United States
Amneal Pharmaceuticals LLC	Amneal Pharmaceuticals LLC	400 Crossing Blvd Third Floor	Bridgewater	NJ	08807	United States
Amphastar Pharmaceuticals, Inc.	Amphastar Pharmaceuticals, Inc.	11570 Sixth Street	Rancho Cucamonga	CA	91730	United States
Amphastar Pharmaceuticals, Inc.	International Medication Systems, LTD	1886 Santa Anita Ave	South El Monte	CA	91733	United States
Amring Pharmaceuticals Inc.	Amring Pharmaceuticals Inc.	1235 Westlakes Drive	Berwyn	PA	19312	United States
Apotex Holdings, Inc.	Apotex Holdings, Inc.	150 Signet Drive	Toronto	Ontario	M9L 1T9	Canada
Apotex Holdings, Inc.	ApoPharma USA, Inc.	2400 N. Commerce Parkway	Weston	FL	33326	United States
Apotex Holdings, Inc.	Apotex Corp.	2400 N. Commerce Parkway	Weston	FL	33326	United States
Apotex Holdings, Inc.	Aveva Drug Delivery Systems, Inc.	2400 N. Commerce Parkway	Weston	FL	33326	United States
Aptevo BioTherapeutics LLC	Aptevo BioTherapeutics LLC	920 Cassatt Road	Berwyn	PA	19312	United States
Aqua Pharmaceuticals an Almirall Company	Aqua Pharmaceuticals an Almirall Company	707 Eagleview Blvd.	Exton	PA	19341	United States
Arbor Pharmaceuticals, Inc.	Arbor Pharmaceuticals, Inc.	6 Concourse Parkway	Atlanta	GA	30328	United States
Arbor Pharmaceuticals, Inc.	Wilshire Pharmaceuticals	6 Concourse Parkway	Atlanta	GA	30328	United States
Ascend Therapeutics US, LLC	Ascend Therapeutics US, LLC	607 Herndon Parkway	Herndon	VA	20170	United States
Astellas Pharma US, Inc.	Astellas Pharma US, Inc.	1 Astellas Way	Northbrook	IL	60062	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
AstraZeneca Pharmaceuticals LP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike	Wilmington	DE	19850- 5437	United States
AstraZeneca Pharmaceuticals LP	AstraZeneca Pharmaceuticals LP	1800 Concord Pike	Wilmington	DE	19850- 5437	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma USA, Inc	279 Princeton Hightstown Road	East Windsor	NJ	08520- 1401	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma Limited	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	Aurobindo Pharma USA Incorporated	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroHealth, LLC	6 Wheeling Road	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroLife Pharma LLC	2400 Rt 130	Dayton	NJ	08810	United States
Aurobindo Pharma USA, Inc	AuroMedics Pharma, LLC	6 Wheeling Road	Dayton	NJ	08810	United States
Avadel Pharmaceuticals (USA), Inc.	Avadel Pharmaceuticals (USA), Inc.	16640 Chesterfield Grove Rd Ste 200	Chesterfield	МО	63005- 1410	United States
Avanir Pharmaceuticals	Avanir Pharmaceuticals	30 Enterprise	Aliso Viejo	CA	92656	United States
B.F. Ascher & Co., Inc.	B.F. Ascher & Co., Inc.	15501 W. 109th St.	Lenexa	KS	66219	United States
Baxter Healthcare Corporation	Baxter Healthcare Corporation	One Baxter Parkway	Deerfield	IL	60015	United States
Bayer HealthCare LLC	Bayer HealthCare LLC	100 Bayer Boulevard	Whippany	NJ	07981- 0915	United States
Bayer HealthCare LLC	Bayer Consumer Care Holdings LLC	100 Bayer Blvd	Whippany	NJ	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Animal Health Inc.	12707 Shawnee Mission Parkway	Shawnee	KS	66216	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals Inc.	100 Bayer Blvd	Whippany	NJ	07981	United States
Bayer HealthCare LLC	Bayer HealthCare Pharmaceuticals LLC	800 Dwight Way	Berkeley	CA	94710	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Bayer HealthCare LLC	MSD Consumer Care Inc.	100 Bayer Boulevard	Whippany	NJ	07981- 0915	United States
Beach Products, Inc.	Pharmaceutical Associates, Inc.			SC		
Beach Products, Inc.	Beach Pharmaceuticals	3010 W. De Leon Street	Tampa	FL	33609	United States
Beach Products, Inc.	Pharmaceutical Associates, Inc.	3010 W. De Leon Street	Tampa	FL	33609	United States
BestCo, Inc.	BestCo, Inc.	288 Mazeppa Road	Mooresville	NC	28027	United States
Biogen Inc.	Biogen Inc.	225 Binney Street	Cambridge	MA	02142	United States
BioMarin Pharmaceutical Inc.	BioMarin Pharmaceutical	105 Digital Drive	Novato	CA	94949	United States
BionPharma Inc.	BionPharma Inc.	600 Alexander Road	Princeton	NJ	08540	United States
BionPharma Inc.	Banner Life Sciences LLC	600 Alexander Rd Ste 2-4B	Princeton	NJ	08540- 6013	United States
Blistex Inc.	Blistex Inc.	1800 Swift Drive	Oak Brook	IL	60523	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim USA, Inc.	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Animal Health Division	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Fremont, Inc.	6701 Kaiser Drive	Fremont	CA	94555	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Pharmaceuticals, Inc.	900 Ridgebury Road	Ridgefield	СТ	06877	United States
Boehringer Ingelheim USA, Inc.	Boehringer Ingelheim Vetmedica, Inc.	2612 Belt Highway	St. Joseph	МО	64506	United States
Boehringer Ingelheim USA, Inc.	Merial Select, Inc.	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States
Boehringer Ingelheim USA, Inc.	Merial, Inc.	3239 Satellite Blvd	Duluth	GA	30096- 4640	United States
Braintree Laboratories Inc.	Braintree Laboratories Inc.	60 Columbian Street West	Braintree	MA	02185- 0929	United States
Braintree Laboratories Inc.	Affordable Pharmaceuticals LLC	60 Columbian St. West Suite 200	Braintree	МА	02185- 0253	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Bristol-Myers Squibb Company	Bristol-Myers Squibb Company	P.O. Box 4500	Princeton	NJ	08543- 4500	United States
Bristol-Myers Squibb Company	Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership	Route 206 & Province Line Road	Princeton	NJ	08540- 4000	United States
Bristol-Myers Squibb Company	E.R. Squibb & Sons, LLC	P.O. Box 4500	Princeton	NJ	08543- 4500	United States
Bristol-Myers Squibb Company	Medarex, LLC	707 State Road	Princeton	NJ	08540- 1437	United States
Bristol-Myers Squibb Company	ZymoGenetics, Inc.	1201 Eastlake Ave E	Seattle	WA	98102	United States
Celgene Corporation	Celgene Corporation	10300 Campus Point Drive	San Diego	CA	92121	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	1255 Crescent Green Drive	Cary	NC	27518	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Aristos Pharmaceuticals, Inc.	1255 Crescent Green Drive	Cary	NC	27518	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Chiesi USA	1255 Crescent Green Drive	Cary	NC	27518	United States
Chiesi USA, Inc. (formerly Cornerstone Therapeutics, Inc.)	Cornerstone Therapeutics Inc.	1255 Crescent Green Drive	Cary	NC	27518	United States
Church & Dwight Company, Inc.	Church & Dwight Company, Inc.	469 N Harrison St	Princeton	NJ	08540- 3597	United States
Clarion Brands LLC	Clarion Brands LLC	27070 Miles Road, Suite A	Solon	ОН	44139	United States
Colgate-Palmolive Company	Colgate-Palmolive Company	300 Park Avenue	New York	NY	10022	United States
Colgate-Palmolive Company	Colgate Oral Pharmaceuticals, Inc.	300 Park Avenue	New York	NY	10022	United States
Concordia Pharmaceuticals Inc.	Concordia Pharmaceuticals Inc.	5 Canewood Industrial Park	Canewood	St. Michael	BB11005	Barbados
Corcept Therapeutics	Corcept Therapeutics	149 Commonwealth Drive	Menlo Park	CA	94025	United States
CSL Behring, LLC	CSL Behring, LLC	1020 1st Ave MB 435-10	King of Prussia	PA	19406- 1310	United States
CutisPharma, Inc.	CutisPharma, Inc.	841 Woburn Street	Wilmington	MA	01887- 3414	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Daiichi Sankyo, Inc.	Daiichi Sankyo, Inc.	211 Mt. Airy Rd.	Basking Ridge	NJ	07920	United States
Daiichi Sankyo, Inc.	American Regent, Inc.	One Luitpold Drive	Shirley	NY	11967	United States
Daiichi Sankyo, Inc.	Luitpold Pharmaceuticals, Inc.	One Luitpold Drive	Shirley	NY	11967	United States
Davion Inc.	Davion Inc.	2 Progress Road	North Brunswick	NJ	08902	United States
Depomed, Inc.	Depomed, Inc.	7999 Gateway Blvd	Newark	CA	94560	United States
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories, Inc	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories Louisiana, LLC	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Dr. Reddy's Laboratories Tennessee, LLC	107 College Road East	Princeton	NJ	08540	United States
Dr. Reddy's Laboratories, Inc	Promius Pharma, LLC	107 College Road East	Princeton	NJ	08540	United States
DSE Healthcare Solutions, LLC	DSE Healthcare Solutions, LLC	105 Fieldcrest Avenue	Edison	NJ	08837	United States
DSE Healthcare Solutions, LLC	Numark Brands, Inc.	105 Fieldcrest Avenue	Edison	NJ	08837	United States
Duchesnay USA, Inc.	Duchesnay USA, Inc.	919 Conestoga Road, Building I	Rosemont	PA	19010	United States
Duchesnay USA, Inc.	Analog Pharma, Inc.	919 Conestoga Road, Building I	Rosemont	PA	19010	United States
Duchesnay USA, Inc.	Duchesnay Inc.	950 Boulevard Michele-Bohec	Blainville	Quebec	J7C 5E2	Canada
Duchesnay USA, Inc.	Medunik USA, Inc.	919 Conestoga Road, Building I	Rosemont	PA	19010	United States
Edgemont Pharmaceuticals LLC	Edgemont Pharmaceuticals LLC	1250 South Capital of Texas Hwy	Austin	TX	78746	United States
Eisai, Inc.	Eisai, Inc.	100 Tice Blvd	Wood Cliff Lake	NJ	07677	United States
Eli Lilly and Company	Eli Lilly and Company	Lilly Corporate Center	Indianapolis	IN	46285	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
EMD Serono, Inc.	EMD Serono, Inc.	One Technology Place	Rockland	MA	02370	United States
Endo Pharmaceuticals Inc.	Endo Pharmaceuticals Inc.	1400 Atwater Drive	Malvern	PA	19355	United States
Endo Pharmaceuticals Inc.	Anchen Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	9601 Jeronimo Road	Irvine	CA	92618- 2025	United States
Endo Pharmaceuticals Inc.	Auxilium Pharmaceuticals, Inc.	640 Lee Road	Chesterbrook	PA	19087	United States
Endo Pharmaceuticals Inc.	BOCA Pharmacals, Inc.	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	DAVA Pharmaceuticals, Inc.	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Generics Bidco I, LLC (d/b/a Par Pharmaceutical)	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Generics Bidco II, LLC (d/b/a Par Pharmaceutical)	3241 & 3700 Woodpark Blvd	Charlotte	NC	28206	United States
Endo Pharmaceuticals Inc.	Innoteq, Inc. (d/b/a Par Pharmaceutical)	555 Lordship Blvd.	Stratford	СТ	06615	United States
Endo Pharmaceuticals Inc.	Par Pharmaceutical Companies, Inc.	One Ram Ridge Rd	Chestnut Ridge	NY	10977	United States
Endo Pharmaceuticals Inc.	Par Pharmaceutical, Inc.	300 Tice Boulevard	Woodcliff Lake	NJ	07677	United States
Endo Pharmaceuticals Inc.	Par Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	One Ram Ridge Rd	Chestnut Ridge	NY	10977	United States
Endo Pharmaceuticals Inc.	Par Sterile Products, LLC (d/b/a Par Pharmaceutical)	970 Parkdale Road	Rochester	MI	48307	United States
Endo Pharmaceuticals Inc.	Quartz Specialty Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	130 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, Inc. (d/b/a Par Pharmaceutical)	130 Vintage Ave	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	120 Vintage Drive	Huntsville	AL	35811	United States
Endo Pharmaceuticals Inc.	Vintage Pharmaceuticals, LLC (d/b/a Par Pharmaceutical)	150 Vintage Drive	Huntsville	AL	35811	United States
Exelixis, Inc.	Exelixis, Inc.	210 E Grand Ave	South San Francisco	CA	94080- 4811	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Exelixis, Inc.	Exelixis US, LLC	210 E Grand Ave	South San Francisco	CA	94080- 4811	United States
Ferring Pharmaceuticals Inc.	Ferring Pharmaceuticals Inc.	100 Interpace Parkway	Parsippany	NJ	07054	United States
Foundation Consumer Healthcare, LLC	Foundation Consumer Healthcare, LLC	1190 Omega Drive	Pittsburgh	PA	15205	United States
Fresenius Kabi USA, LLC	Fresenius Kabi USA, LLC	Three Corporate Drive	Lake Zurich	IL	60047	United States
G&W Laboratories, Inc.	G&W Laboratories, Inc.	111 Coolidge Street	South Plainfield	NJ	07080	United States
G&W Laboratories, Inc.	G&W NC Laboratories LLC	1877 Kawai Rd	Lincolnton	NC	28092	United States
G&W Laboratories, Inc.	G&W PA Laboratories LLC	650 Cathill Rd	Sellersville	PA	18960	United States
Galderma Laboratories, L.P.	Galderma Laboratories, L.P.	14501 North Freeway	Fort Worth	TX	76177	United States
Garcoa Laboratories, Inc.	Garcoa Laboratories	26135 Mureau Road	Calabasas	CA	91302	United States
Gemini Laboratories, LLC	Gemini Laboratories, LLC	Graymark at Bridgewater	Bridgewater	NJ	08807- 2943	United States
Genus Lifesciences Inc.	Genus Lifesciences Inc.	514 North 12th Street	Allentown	PA	18102	United States
Gilead Sciences, Inc.	Gilead Sciences, Inc.	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences Limited	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences, Inc.	333 Lakeside Drive	Foster City	CA	94404	United States
Gilead Sciences, Inc.	Gilead Sciences, LLC	333 Lakeside Drive	Foster City	CA	94404	United States
GlaxoSmithKline, LLC	GlaxoSmithKline, LLC	5 Crescent Drive	Philadelphia	PA	19112	United States
GlaxoSmithKline, LLC	GlaxoSmithKline Consumer Healthcare LP	184 Liberty Corner Road	Warren	NJ	07059	United States
GlaxoSmithKline, LLC	GlaxoSmithKline Holdings (US) LLC	5 Crescent Drive	Philadelphia	PA	19112	United States
GlaxoSmithKline, LLC	Novartis Consumer Health, Inc.	200 Kimball Drive	Parsippany	NJ	07054	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
GlaxoSmithKline, LLC	Stiefel Laboratories, Inc.	20 TW Alexander Dr	Research Triangle Park	NC	27709	United States
GlaxoSmithKline, LLC	ViiV Healthcare Company	5 Moore Drive	RTP	NC	27709	United States
Glenmark Pharmaceuticals Inc., USA	Glenmark Pharmaceuticals Inc., USA	750 Corporate Drive	Mahwah	NJ	07430	United States
Grifols Shared Services North America Inc.	Grifols Shared Services North America Inc.	2410 Lillyvale Avenue	Los Angeles	CA	90032	United States
Grifols Shared Services North America Inc.	Grifols Biologicals LLC	5555 Valley Blvd.	Los Angeles	CA	90032	United States
Grifols Shared Services North America Inc.	Grifols Therapeutics LLC	8368 US 70 Business Hwy West	Clayton	NC	27520	United States
Grifols Shared Services North America Inc.	Instituto Grifols S.A.	Poligono Industrial Levante	Parets Del Valles	Barcelona	08150	Spain
Grifols Shared Services North America Inc.	Laboratorios Grifols S.A.	Calle Logistica 2	Parets del Valles	Barcelona	08150	Spain
Grifols Shared Services North America Inc.	Talecris Biotherapeutics, Inc.	2410 Lillyvale Avenue	Los Angeles	CA	90032	United States
Harris Pharmaceutical, Inc.	Harris Pharmaceutical, Inc.	9090 Park Royal Drive	Ft. Myers	FL	33908	United States
Heritage Pharmaceuticals Inc.	Heritage Pharmaceuticals Inc.	12 Christopher Way	Eatontown	NJ	07724	United States
Horizon Pharma plc.	Horizon Pharma plc.	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Orphan LLC	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Pharma Rheumatology LLC (formerly known as Crealta Pharmaceuticals LLC)	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Pharma USA, Inc.	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	Horizon Therapeutics, Inc.	150 S. Saunders Rd.	Lake Forest	IL	60045	United States
Horizon Pharma plc.	HZNP USA, Inc.	150 Saunders Rd	Lake Forest	IL	60045- 2509	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Humco Holding Group, Inc.	Humco Holding Group, Inc.	7400 Alumax Rd	Texarkana	TX	75501- 0282	United States
Impax Laboratories, Inc.	Impax Laboratories, Inc.	602 Office Center Drive	Fort Washington	PA	19034	United States
Impax Laboratories, Inc.	Amedra Laboratories LLC	2 Walnut Grove Drive	Horsham	PA	19044- 2219	United States
Impax Laboratories, Inc.	CorePharma, LLC	215 Wood Avenue	Middlesex	NJ	08846	United States
Impax Laboratories, Inc.	Impax Laboratories (Taiwan), Inc. Jhunan Science Park	No.1, Ke Dong 3rd Road 350	Jhunan	MiaoLing County		Taiwan, Province of China
Impax Laboratories, Inc.	Lineage Therapeutics Inc.	2 Walnut Grove	Horsham	PA	19044	United States
Incyte Corporation	Incyte Corporation	Attn: Incyte Corporation	Indianapolis	IN	46241	United States
Indivior Inc	Indivior Inc	10710 Midlothian Turnpike, Suite 430	Richmond	VA	23235	United States
Ingenus Pharmaceuticals, LLC	Ingenus Pharmaceuticals, LLC	4190 Millenia Blvd.	Orlando	FL	32839	United States
Intergel Pharmaceuticals Inc.	International Vitamin Corporation	500 Halls Mill Rd	Freehold	NJ	07728- 8811	United States
Invagen Pharmaceuticals, Inc.	Cipla USA, Inc.	7 Oser Avenue	Hauppauge	NY	11788	United States
Invagen Pharmaceuticals, Inc.	Cipla USA, Inc.	1560 Sawgrass Corporate Parkway	Sunrise	FL	33323	United States
Ipsen Biopharmaceuticals, Inc	Ipsen Biopharmaceuticals, Inc	106 Allen Road	Basking Ridge	NJ	07920	United States
Iroko Pharmaceuticals, LLC	Iroko Pharmaceuticals, LLC	150 Rouse Boulevard	Philadelphia	PA	19112	United States
Ironwood Pharmaceuticals, Inc.	Ironwood Pharmaceuticals, Inc.	301 Binney Street	Cambridge	MA	02142	United States
Jacobus Pharmaceutical Company, Inc.	Jacobus Pharmaceutical Company, Inc.	37 Cleveland Ln PO Box 5290	Princeton	NJ	08540- 3090	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Jazz Pharmaceuticals, plc	Jazz Pharmaceuticals, plc	Fourth Floor, Connaught House	Dublin		4	Ireland
Jazz Pharmaceuticals, plc	Jazz Pharmaceuticals, Inc.	3180 Porter Drive	Palo Alto	CA	94304	United States
Jazz Pharmaceuticals, plc	Jazz Pharmaceuticals, International Division	Wing B, Building 5700	Oxford Business Park South	Oxford	OX4 2RW	United Kingdom
Johnson & Johnson	Johnson & Johnson	One Johnson & Johnson Plaza	New Brunswick	NJ	08933	United States
Johnson & Johnson	Janssen Biotech, Inc.	800/850 Ridgeview Drive	Horsham	PA	19044	United States
Johnson & Johnson	Janssen Pharmaceuticals, Inc.	1125 Trenton- Harbourton Road	Titusville	NJ	08560	United States
Johnson & Johnson	Janssen Products, LP	800/850 Ridgeview Dr.	Horsham	PA	19044	United States
Johnson & Johnson	Johnson & Johnson Consumer, Inc.	199 Grandview Road	Skillman	NJ	08558	United States
Johnson & Johnson	McNeil Consumer Healthcare Latin America LLC	7050 Camp Hill Road	Fort Washington	PA	19034	United States
Johnson & Johnson	McNeil Consumer Pharmaceuticals Co.	7050 Camp Hill Rd	Fort Washington	PA	19034- 2299	United States
Johnson & Johnson	McNeil Healthcare LLC	Road 183 KM 19.8	Barrio Montones	Las Piedras	00771	Puerto Rico
Johnson & Johnson	McNeil MMP, LLC	One Johnson & Johnson Plaza	New Brunswick	NJ	08933	United States
Johnson & Johnson	McNeil Nutritionals LLC	7050 Camp Hill Road	Fort Washington	PA	19034	United States
Johnson & Johnson	McNeil-PPC, Inc.					
Johnson & Johnson	Ortho-McNeil Finance LLC	6018 Bowendale Avenue	Jacksonville	FL	32216- 0995	United States
Johnson & Johnson	Patriot Pharmaceuticals, LLC	200 Tournament Drive	Horsham	PA	19044	United States
Jubilant Cadista Pharmaceuticals Inc.	Jubilant Cadista Pharmaceuticals Inc.	207 Kiley Drive	Salisbury	MD	21801	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Kadmon Corporation, LLC	Kadmon Corporation, LLC	119 Commonwealth Dr	Warrendale	PA	15086- 7503	United States
Kadmon Corporation, LLC	Kadmon Pharmaceuticals, LLC	1450 East 29th Street, 5th Floor	New York	NY	10016	United States
Kaleo Inc.	Kaleo Inc.	111 Virginia Street Suite 300	Richmond	VA	23219	United States
Kowa Pharmaceuticals America, Inc.	Kowa Pharmaceuticals America, Inc.	530 Industrial Park Blvd.	Montgomery	AL	36117	United States
L. Perrigo Company	L. Perrigo Company	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Athena Neurosciences, LLC	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Cobrek Pharmaceuticals, Inc.	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Elan Pharmaceuticals, LLC	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Paddock Laboratories, LLC	3940 Quebec Ave	Minneapolis	MN	55427	United States
L. Perrigo Company	Perrigo Company of Tennessee	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Perrigo Corporation Designated Activity Company	Treasury Building	Lower Grand Canal St.	Dublin	2	Ireland
L. Perrigo Company	Perrigo Florida, Inc.	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Perrigo LLC	515 Eastern Avenue	Allegan	MI	49010	United States
L. Perrigo Company	Perrigo New York, Inc.	1625 Bathgate Avenue	Bronx	NY	10457	United States
L. Perrigo Company	Perrigo Pharma International Designated Activity Company	Treasury Building, Lower Grand Canal St.	Dublin		2	Ireland
L. Perrigo Company	Perrigo Pharmaceuticals Company	515 Eastern Avenue	Allegan	MI	49010	United States
Lannett Company, Inc.	Lannett Company, Inc.	13200 Townsend Rd	Philadelphia	PA	19154	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Lannett Company, Inc.	Cody Laboratories	601 Yellowstone Avenue	Cody	WY	82414	United States
Lannett Company, Inc.	Kremers Urban Pharmaceuticals Inc.	1101 C Avenue West	Seymour	IN	47274	United States
Lannett Company, Inc.	Silarx Pharmaceuticals	1033 Stoneleigh Avenue	Carmel	NY	10512	United States
Leadiant Biosciences, Inc.	Leadiant Biosciences, Inc.	9841 Washingtonian Blvd.	Gaithersburg	MD	20878	United States
LEO Pharma A/S	LEO Pharma A/S	7 Giralda Farms 2nd Floor	Madison	NJ	07940	United States
LEO Pharma A/S	LEO Pharma Inc.	7 Giralda Farms	Madison	NJ	07940	United States
LF Beauty/ Lornamead	LF Beauty/ Lornamead	1359 Broadway	New York	NY	10018	United States
LF Beauty/ Lornamead	Lornamead Inc.	175 Cooper Avenue	Tonawanda	NY	14150	United States
Lundbeck LLC	Lundbeck LLC	Six Parkway N Ste 400	Deerfield	IL	60015	United States
Lupin Pharmaceuticals. Inc	Lupin Pharmaceuticals. Inc	111 S. Calvert St.	Baltimore	MD	21202	United States
Lupin Pharmaceuticals. Inc	GAVIS Pharma LLC	400 Campus Drive	Somerset	NJ	08873	United States
Lupin Pharmaceuticals. Inc	GAVIS Pharmaceuticals LLC	400 Campus Drive	Somerset	NJ	08873	United States
Lupin Pharmaceuticals. Inc	Lupin Ltd.					
Lupin Pharmaceuticals. Inc	Lupin Pharmaceuticals, Inc.	111 S. Calvert St.	Baltimore	MD	21202	United States
Lupin Pharmaceuticals. Inc	Novel Laboratories Inc.	400 Campus Drive	Somerset	NJ	08873	United States
Mallinckrodt Pharmaceuticals	Mallinckrodt Pharmaceuticals	675 McDonnell Blvd.	Hazelwood	МО	63042	United States
Matrixx Initiatives, Inc.	Matrixx Initiatives, Inc.	440 Rt. 22 E	Bridgewater	NJ	08807	United States
Mayne Pharma Inc.	Mayne Pharma Inc.	1240 Sugg Parkway	Greenville	NC	27834	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Mayne Pharma Inc.	Libertas Pharma Inc	1240 Sugg Parkway	Greenville	NC	27834	United States
Mayne Pharma Inc.	Metrics Inc DBA Mayne Pharma	1240 Sugg Parkway	Greenville	NC	27834	United States
Merck & Co., Inc.	Merck & Co., Inc.	2000 Galloping Hill Road	Kenilworth	NJ	07033	United States
Merck & Co., Inc.	Cherokee Pharmaceutical LLC	100 Avenue C	Riverside	PA	17868	United States
Merck & Co., Inc.	Cubist Pharmaceuticals	55 Hayden Avenue	Lexington	MA	02421	United States
Merck & Co., Inc.	Intervet, Inc., doing business as Merck Animal Health	2 Giralda Farms	Madison	NJ	07940	United States
Merck & Co., Inc.	Merck Sharp & Dohme Corp.	2000 Galloping Hill Rd	Kenilworth	NJ	07033- 1328	United States
Merck & Co., Inc.	Organon Teknika Corporation, LLC	100 Rudolphe St	Durham	NC	37172	United States
Merck & Co., Inc.	Organon Teknika LLC	100 Rodolphe Street	Durham	NC	37172	United States
Merz North America, Inc.	Merz North America, Inc.	6501 Six Forks Road	Raleigh	NC	27615	United States
Merz North America, Inc.	Merz N.A. f/k/a Merz Aesthetics, Inc	6501 Six Forks Road	Raleigh	NC	27615	United States
Merz North America, Inc.	Merz North America, Inc.	1340 Grandview Parkway	Sturtevant	WI	53177	United States
Merz North America, Inc.	Merz Pharmaceuticals, LLC	6501 Six Forks Road	Raleigh	NC	27615	United States
Midatech Pharma US Inc.	Midatech Pharma US Inc.	8601 Six Forks Road	Raleigh	NC	27615	United States
Mikart, Inc.	Mikart, Inc.	1750 Chatahoochee Ave NW	Atlanta	GA	30318	United States
Mission Pharmacal Company	Mission Pharmacal Company	P.O. Box 786099	San Antonio	TX	78278- 6099	United States
Mission Pharmacal Company	Prosolus, Inc.	6701 NW 7th St Ste 165	Miami	FL	33126- 6032	United States
Mist Pharmaceuticals, LLC	Mist Pharmaceuticals, LLC	11 Commerce Drive, Suite 100	Cranford	NJ	07016	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Mylan Inc.	Mylan Inc.	1000 Mylan Boulevard	Canonsburg	PA	15317	United States
Mylan Inc.	Alphapharm Pty Ltd	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	DPT Laboratories LTD (DD)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	DPT Laboratories LTD (JS)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Meda Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Consumer Healthcare, Inc. (fka Meda Consumer Healthcare Inc.)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Galway	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Inc. (IL)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional Inc. (TX)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Institutional LLC	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (1606- 1609JP)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (20/21JP)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (BL)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Mylan Inc.	Mylan Laboratories Limited (F4/F12OSD)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (H12/H13OSD)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (OTL)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SF)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SFF)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Laboratories Limited (SPD)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan LLC	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Specialty L.P.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan Technologies, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Mylan.D.T., Inc. (fka Renaissance Pharma, Inc.)	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Prestium Pharma, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Mylan Inc.	Somerset Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Mylan Inc.	Wallace Pharmaceuticals, Inc.	C/O Joseph Shepherd Reg Affs	Morgantown	WV	26505- 2772	United States
Neos Therapeutics, Inc.	Neos Therapeutics, Inc.	2940 N State Highway 360 Ste 400	Grand Prairie	TX	75050- 6424	United States
Neos Therapeutics, Inc.	Neos Therapeutics Brand LLC	2940 N. State Highway 360	Grand Prairie	TX	75050	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation	4500 12th Street Ext	West Columbia	SC	29172- 3025	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 1	840 S. 67th Avenue	Phoenix	AZ	85043	United States
Nephron Pharmaceuticals Corporation	Nephron Pharmaceuticals Corporation - Distribution Center 2	78 Spruce Street	Murray	KY	42071	United States
Neurocrine Biosciences, Inc.	Neurocrine Biosciences, Inc.	12780 El Camino Real	San Diego	CA	92130	United States
Nexgen Pharma, Inc.	Nexgen Pharma, Inc.	46 Corporate Park	Irvine	CA	92606	United States
NEXTSOURCE BIOTECHNOLOGY LLC	NEXTSOURCE BIOTECHNOLOGY LLC	80 SW 8th St Ste 2660	Miami	FL	33130	United States
Novartis Group Companies	Novartis Group Companies	59 Route 10	East Hanover	NJ	07936	United States
Novartis Group Companies	Alcon Laboratories, Inc.	6740 Business Parkway	Elkridge	MD	21075	United States
Novartis Group Companies	Eon Labs, Inc.	4700 Sandoz Drive	Wilson	NC	27893	United States
Novartis Group Companies	Fougera Pharmaceuticals Inc.	60 Baylis Road	Melville	NY	11747	United States
Novartis Group Companies	Novartis Pharmaceuticals Corporation	1 Health Plaza	East Hanover	NJ	07936- 1016	United States
Novartis Group Companies	Sandoz Inc.	100 College Road West	Princeton	NJ	08540	United States
Noven Pharmaceuticals, Inc.	Noven Pharmaceuticals, Inc.	11960 SW 144th St	Miami	FL	33186	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Noven Pharmaceuticals, Inc.	Hisamitsu America, Inc.	100 Campus Drive	Florham Park	NJ	07932	United States
Noven Pharmaceuticals, Inc.	Noven Therapeutics, LLC	11960 NW 144th St	Miami	FL	33186	United States
Novo Nordisk Inc.	Novo Nordisk Inc.	800 Scudders Mill Road	Plainsboro	NJ	08536	United States
Optinose US, Inc.	Optinose US, Inc.	1020 Stony Hill Road	Yardley	PA	19067	United States
OrchidPharma, Inc.	OrchidPharma, Inc.	100 Overlook Center	Princeton	NJ	08540	United States
OrchidPharma, Inc.	Orchid Pharma Ltd.	313 Valluvar Kottam High Rd	Nungambakkam	Chennai	600 034	India
Orexigen Therapeutics, Inc.	Orexigen Therapeutics, Inc.	3344 N. Torrey Pines Court	La Jolla	CA	92037	United States
Otsuka America Pharmaceutical, Inc.	Otsuka America Pharmaceutical, Inc.	508 Carnegie Center	Princeton	NJ	08540	United States
PARI Respiratory Equipment, Inc.	PARI Respiratory Equipment, Inc.	2412 Pari Way	Midlothian	VA	23112	United States
Pegasus Laboratories, Inc.	Pegasus Laboratories, Inc.	8809 Ely Road	Pensacola	FL	32514	United States
Pfizer Inc.	Pfizer Inc.	235 East 42nd Street	New York	NY	10017	United States
Pfizer Inc.	Greenstone LLC	100 Route 206 North	Peapack	NJ	07977	United States
Pfizer Inc.	Hospira	275 N. Fields Drive	Lake Forest	IL	60045	United States
Pfizer Inc.	Meridian Medical Technologies, Inc.	8030 Litzinger Road	St. Louis	МО	63144	United States
Pfizer Inc.	Pfizer Consumer Health	235 East 42nd Street	New York	NY	10017	United States
Pharmasphere, Inc.	Pharmasphere, Inc.	120 Route 17 North	Paramus	NJ	07652	United States
Pharmasphere, Inc.	Pharma-C, LLC	120 Route 17 North	Paramus	NJ	07652	United States
Pharmasphere, Inc.	WG Critical Care, LLC	120 Route 17 North	Paramus	NJ	07652	United States
Pharming Healthcare Inc.	Pharming Healthcare Inc.	685 Route 202/206	Bridgewater	NJ	08807	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Prestige Brands Holdings, Inc.	Prestige Brands Holdings, Inc.	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Brands Holdings, Inc.	C.B. Fleet Company, Inc.	4615 Murray Place	Lynchburg	VA	24502	United States
Prestige Brands Holdings, Inc.	C.B. Fleet Company, Incorporated	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Brands Holdings, Inc.	DenTek Oral Care, Inc.	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Brands Holdings, Inc.	Insight Pharmaceuticals Corporation	660 White Plains Rd Ste 250	Tarrytown	NY	10591- 5171	United States
Prestige Brands Holdings, Inc.	Insight Pharmaceuticals LLC	660 White Plains Road,2nd Floor	Tarrytown	NY	10591	United States
Prestige Brands Holdings, Inc.	Medtech Products Inc.	660 White Plains Road, 2nd Floor	Tarrytown	NY	10591	United States
Prestige Brands Holdings, Inc.	Prestige Brands, Inc.	660 White Plains Road	Tarrytown	NY	10591	United States
Primus Pharmaceuticals, Inc.	Primus Pharmaceuticals, Inc.	7373 N Scottsdale Rd. B-200	Scottsdale	AZ	85253	United States
Product Quest Mfg.	Product Quest Mfg.	330 Carswell Avenue	Daytona Beach	FL	32117	United States
PuraCap International, LLC	PuraCap International, LLC	20 Kingsbridge Rd.	Piscataway	NJ	08854	United States
PuraCap International, LLC	Epic Pharma, LLC	227-15N	Laurelton	NY	11413	United States
PuraCap International, LLC	PuraCap Caribe	Carr 698 km 0.8	Bo Mameyal Dorado	Puerto Rico	00646	Puerto Rico
PuraCap International, LLC	PuraCap Laboratories LLC dba Blu Pharmaceuticals	301 Robey St.	Franklin	KY	42134	United States
PuraCap International, LLC	PuraCap Pharmaceuticals, LLC	20 Kingsbridge Rd	Piscataway	NJ	08854	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Purdue Pharma L.P.	Purdue Pharma L.P.	One Stamford Forum	Stamford	СТ	06901	United States
Purdue Pharma L.P.	Purdue Pharmaceuticals L.P.	4701 Purdue Drive	Wilson	NC	27893	United States
Purdue Pharma L.P.	Purdue Products L.P.	One Stamford Forum	Stamford	СТ	06901	United States
Purdue Pharma L.P.	Rhodes Pharmaceuticals L.P.	498 Washington Street	Coventry	RI	02816	United States
Putney, Inc.	Putney, Inc.	One Monument Square	Portland	ME	04101	United States
Reckitt Benckiser LLC	Reckitt Benckiser LLC	399 Interpace Parkway	Parsippany	NJ	07054	United States
Regeneron Pharmaceuticals, Inc	Regeneron Pharmaceuticals, Inc	777 Old Saw Mill River Rd	Tarrytown	NY	10591	United States
Regeneron Pharmaceuticals, Inc	Regeneron Healthcare Solutions, Inc	745 Old Saw Mill River Rd	Tarrytown	NY	10591	United States
Roche Holdings	Roche Holdings	1 Dna Way	South San Francisco	CA	94080- 4918	United States
Roche Holdings	Genentech USA	Genetech, Inc.	South San Francisco	CA	94080- 4990	United States
Roche Holdings	Genentech, Inc.	Hoffman-La Roche Inc.	South San Francisco	CA	94080- 4990	United States
Rouses Point Pharmaceuticals, LLC	Rouses Point Pharmaceuticals, LLC	11 Commerce Drive, First Floor	Cranford	NJ	07016	United States
Sanofi-Aventis US LLC.	Sanofi-Aventis US LLC.	55 Corporate Drive	Bridgewater	NJ	08807	United States
Sanofi-Aventis US LLC.	Chattem, Inc.	1715 West 38th St.	Chattanooga	TN	37409	United States
Sebela Pharmaceuticals Inc.	Sebela Pharmaceuticals Inc.	645 Hembree Pkwy	Roswell	GA	30076	United States
Shionogi Inc.	Shionogi Inc.	300 Campus Dr.	Florham Park	NJ	07932	United States
Shire Pharmaceuticals LLC	Shire Pharmaceuticals LLC	300 Shire Way	Lexington	MA	02421	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Shire Pharmaceuticals LLC	Baxalta US Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Dyax Corporation	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire Human Genetic Therapies, Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire LLC	9200 Brookfield Court	Florence	KY	41042	United States
Shire Pharmaceuticals LLC	Shire NPS Pharmaceuticals (f/k/a NPS Pharmaceuticals, Inc.)	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire Orphan Therapies Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire US Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	Shire US Manufacturing Inc.	1200 Morris Drive	Wayne	PA	19087	United States
Shire Pharmaceuticals LLC	Shire ViroPharma, Inc.	300 Shire Way	Lexington	MA	02421	United States
Shire Pharmaceuticals LLC	ViroPharma Biologics Inc.	300 Shire Way	Lexington	MA	02421	United States
SigmaPharm Laboratories LLC	SigmaPharm Laboratories LLC	3375 Progress Drive	Bensalem	PA	19020	United States
Silvergate Pharmaceuticals, Inc.	Silvergate Pharmaceuticals, Inc.	7300 W 110th St Ste 950	Overland Park	KS	66210- 2394	United States
Smith & Nephew Inc (Smith & Nephew Biotherapeutics)	Smith & Nephew Inc (Smith & Nephew Biotherapeutics)	Attn: David Mize, VP Dist, Finance	Ft. Worth	TX	76107	United States
Stallergenes Greer	Stallergenes Greer	55 Cambridge Parkway	Cambridge	MA	02142	United States
Strides Shasun Limited	Strides Shasun Limited	Strides House	BANGALURU	Karnataka State	560076	India
Sun Pharmaceutical Industries, Inc.	Sun Pharmaceutical Industries, Inc.	270 Prospect Plains Road	Cranbury	NJ	08512	United States
Sun Pharmaceutical Industries, Inc.	AR Scientific, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	Caraco Pharma, Inc.	270 Prospect Plains Road	Cranbury	NJ	08512	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Sun Pharmaceutical Industries, Inc.	Chattem Chemicals, Inc.	3708 St. Elmo Avenue	Chattanooga	TN	37409	United States
Sun Pharmaceutical Industries, Inc.	Dungan Mutual Associates, LLC	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	DUSA Pharmaceuticals New York, Inc.	25 Upton Drive	Wilmington	MA	01887	United States
Sun Pharmaceutical Industries, Inc.	DUSA Pharmaceuticals, Inc.	25 Upton Drive	Wilmington	MA	01887	United States
Sun Pharmaceutical Industries, Inc.	Mutual Pharmaceutical Company, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	Ohm Laboratories Inc.	14 Terminal Road	New Brunswick	NJ	08901	United States
Sun Pharmaceutical Industries, Inc.	Pharmalucence, Inc.	29 Dunham Road	Billerica	MA	01821	United States
Sun Pharmaceutical Industries, Inc.	Ranbaxy Laboratories Limited	600 College Road East	Princeton	NJ	08540	United States
Sun Pharmaceutical Industries, Inc.	Sirius Laboratories, Inc.	25 Upton Drive	Wilmington	MA	01887	United States
Sun Pharmaceutical Industries, Inc.	Taro Pharmaceuticals U.S.A., Inc.	3 Skyline Drive	Hawthorne	NY	10532	United States
Sun Pharmaceutical Industries, Inc.	United Research Laboratories, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	URL Pharma, Inc.	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sun Pharmaceutical Industries, Inc.	URL PharmPro, LLC	1100 Orthodox St.	Philadelphia	PA	19124	United States
Sunovion Pharmaceuticals Inc.	Sunovion Pharmaceuticals Inc.	84 Waterford Dr	Marlborough	MA	01752- 7010	United States
Sunstar Americas, Inc.	Sunstar Americas, Inc.	301 East Central Road	Schaumburg	IL	60195	United States
Supernus Pharmaceuticals, Inc.	Supernus Pharmaceuticals, Inc.	1550 E. Gude Drive	Rockville	MD	20850	United States
Takeda Pharmaceuticals U.S.A., Inc.	Takeda Pharmaceuticals America, Inc.	One Takeda Parkway	Deerfield	IL	60015	United States
Takeda Pharmaceuticals U.S.A., Inc.	Millennium Pharmaceuticals, Inc. (d/b/a Takeda Oncology)	40 Lansdowne Street	Cambridge	MA	02139	United States
Takeda Pharmaceuticals U.S.A., Inc.	Takeda Pharmaceuticals America, Inc.	One Takeda Parkway	Deerfield	IL	60015	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Tec Laboratories, Inc.	Tec Laboratories, Inc.	7100 Tec Labs Way SW	Albany	Oregon	97321	United States
TESARO, Inc.	TESARO, Inc.	1000 Winter Street North, Suite 3300	Waltham	MA	02451	United States
Teva Pharmaceuticals USA, Inc.	Teva Pharmaceuticals USA, Inc.	1090 Horsham Rd	North Wales	PA	19454- 1505	United States
Teva Pharmaceuticals USA, Inc.	Actavis Generics	400 Interpace Pkwy	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Barr Pharmaceuticals, Inc.	Morris Corporate Center III	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Cephalon, Inc.	Morris Corporate Center III	Parsippany	NJ	07054	United States
Teva Pharmaceuticals USA, Inc.	Teva Neuroscience Inc.	11100 Nail Ave	Overland Park	KS	66221	United States
The Mentholatum Company	The Mentholatum Company	707 Sterling Drive	Orchard Park	NY	14127	United States
The Mentholatum Company	Mentholatum (China) Pharmaceuticals Co., Ltd.	The Second Industrial Estates	Sanxiang, Zhongshan	Guangdong	528463	China
The Mentholatum Company	Rohto Pharmaceutical Co. Ltd.	7-3 Yumegaoka, Ige	Mie		518- 0131	Japan
The Procter & Gamble Company	The Procter & Gamble Company	1 Procter & Gamble Plaza	Cincinnati	ОН	45202	United States
The Procter & Gamble Company	The Procter & Gamble Manufacturing Company	1 Procter & Gamble Plaza	Cincinnati	ОН	45202	United States
The Ritedose Corporation (TRC)	The Ritedose Corporation (TRC)	1 Technology Circle	Columbia	SC	29203	United States
Theratechnologies Inc.	Theratechnologies Inc.	2015 Peel Street, 5th Floor	Montreal	Quebec	H3A1T8	Canada
TOLMAR, Inc.	TOLMAR, Inc.	701 Centre Avenue	Fort Collins	со	80526	United States
Trigen Laboratories, LLC	Trigen Laboratories, LLC	400 Crossing Blvd	Bridgewater	NJ	08807	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Trigen Laboratories, LLC	Vertical Pharmaceuticals, LLC	2500 Main Street Extension, Suite 6	Sayreville	NJ	08872	United States
UCB Inc.	UCB Inc.	1950 Lake Park Drive	Smyrna	GA	30080	United States
UCB Inc.	Upstate Pharma LLC	1950 Lake Park Drive	Smyrna	GA	30080	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Pharmaceuticals (USA), Inc.	777 Terrace Avenue	Hasbrouck Heights	NJ	07664	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Laboratories Limited	777 Terrace Aveneu	Hasbrouk Heights	NJ	07604	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Laboratories Limited	777 Terrace Avenue	Hasbrouck Heights	NJ	07604	United States
Unichem Pharmaceuticals (USA), Inc.	Unichem Pharmaceuticals (USA), Inc.	777 Terrace Avenue	Hasbrouck Heights	NJ	07664	United States
Upsher-Smith Laboratories, LLC	Upsher-Smith Laboratories, LLC	6701 Evenstad Dr.	Maple Grove	MN	55369	United States
Valeant Pharmaceuticals International	Valeant Pharmaceuticals International	400 Somerset Corporate Blvd	Bridgewater	NJ	08807	United States
Valeant Pharmaceuticals International	Bausch + Lomb	1400 N. Goodman St.	Rochester	NY	14609	United States
Valeant Pharmaceuticals International	Salix	400 Somerset Corporate Blvd	Bridgewater	NJ	08807	United States
Validus Pharmaceuticals LLC	Validus Pharmaceuticals LLC	119 Cherry Hill Road, Ste 310	Parsippany	NJ	07054	United States
Vertex Pharmaceuticals Incorporated	Vertex Pharmaceuticals Incorporated	50 Northern Avenue	Boston	MA	02210	United States
Vi-Jon, Inc.	Vi-Jon, Inc.	8515 Page Ave	St. Louis	МО	63114	United States
VIVUS, Inc.	VIVUS, Inc.	900 E Hamilton Ave Ste 550	Campbell	CA	95008- 0643	United States
WellSpring Pharmaceutical Corporation	WellSpring Pharmaceutical Corporation	5911 N. Honore Avenue	Sarasota	FL	34243	United States
Welmedix Consumer Healthcare	Welmedix Consumer Healthcare	103 Carnegie Center	Princeton	NJ	08540	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceuticals, Inc./A Hikma Company	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
West-Ward Pharmaceuticals, Inc./A Hikma Company	Al Jazeera Pharmaceutical Industries Ltd	P.O. Box 106229	Riyadh		11666	Saudi Arabia
West-Ward Pharmaceuticals, Inc./A Hikma Company	Al Jazeera Pharmaceutical Industries Ltd	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Hikma Americas	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Hikma Farmaceutica, S.A.	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Hikma International Pharmaceuticals LLC	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Hikma Pharmaceuticals LLC	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Hikma Pharmaceuticals PLC	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	Thymoorgan Pharmazie GmbH	Schiffgraben 23	D-38690 Vienenburg		00000	Germany
West-Ward Pharmaceuticals, Inc./A Hikma Company	Thymoorgan Pharmazie GmbH	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceutical Headquarters & Orals Manufacturing	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceutical—Distribution Warehouse	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceutical—Injectable Manufacturing Facility	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceuticals Corp.—Non- Injectables Manufacturing Facility	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceuticals International Limited	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
West-Ward Pharmaceuticals, Inc./A Hikma Company	West-Ward Pharmaceuticals—Research & Development	2 Esterbrook Lane	Cherry Hill	NJ	08003	United States
Wisconsin Pharmacal Company, LLC	Wisconsin Pharmacal Company, LLC	1 Pharmacal Way	Jackson	WI	53037	United States
Wisconsin Pharmacal Company, LLC	Lake Consumer Products, Inc. (subsidiary of Wisconsin Pharmacal)	1 Pharmacal Way	Jackson	WI	53037	United States
Wockhardt USA LLC	Wockhardt USA LLC	20 Waterview Blvd, 3rd Floor	Parsippany	NJ	07054	United States
Wockhardt USA LLC	Morton Grove Pharmaceuticals, Inc.	6451 Main Street	Morton Grove	IL	60053	United States

Parent Company	Company Name	Address	City	ST	Zip	Country
Wockhardt USA LLC	Wockhardt Limited	Wockhardt Towers	Bandra (E)	Mumbai	400051	India
Wockhardt USA LLC	Wockhardt USA LLC	20 Waterview Blvd.	Parsippany	NJ	07054	United States
X-GEN Pharmaceuticals, Inc.	X-GEN Pharmaceuticals, Inc.	300 Daniel Zenker Drive	Horseheads	NY	14845	United States
Xttrium Laboratories, Inc.	Xttrium Laboratories, Inc.	1200 E. Business Center Dr	Mount Prospect	IL	60056	United States
Zoetis	Zoetis	One Pfizer Way	Lee's Summit	МО	64081	United States
Zydus Pharmaceuticals USA Inc	Zydus Pharmaceuticals USA Inc	73 Route 31 North	Pennington	NJ	08534	United States

Appendix B

Sample Contact List for Outreach and Education to the Community

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

Health Systems:

San Francisco Health Network

University of San Francisco Medical Center

UCSF Benioff Children's Hospital

Zuckerberg San Francisco General Hospital and Trauma Center

Kaiser Permanente San Francisco Medical Center

Dignity Health (St. Francis, St. Mary's)

Sutter Health (Campuses: California, Davies, Pacific, St. Luke's)

San Francisco Chinese Hospital

San Francisco VA Health System

Laguna Honda Hospital and Rehabilitation Center

Langley Porter Psychiatric Hospital and Clinics

One Medical Group

Golden Gate Urgent Care

Health Associations and Societies:

California State Board of Pharmacy

California Pharmacists Association

The Medical Board of California

California Nurses Association

National Association of Social Workers California Chapter

California Board of Registered Nursing

California Board of Vocational Nursing

California Department of Health Care Services

California Health and Human Services Agency

Pharmacist's Society of San Francisco

San Francisco Medical Society

Organizations, Districts, and Agencies:

San Francisco Department of Public Health

San Francisco Environment Department

San Francisco Unified School District

San Francisco Public Utilities Commission

Human Services Agency of San Francisco

University Systems and Campuses

San Francisco Fire Department

American Medical Response San Francisco

CalRecycle

Recology

RecycleWhere.org

Appendix C

Participating Kiosk Drop-Off Sites and Mail-Back Distribution Locations

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
KAISER FRENCH OUTPATIENT PHY 322	4141 GEARY BLVD FIRST FLOOR	94118	1	Kiosk Drop-Off Site
NEMS-NORIEGA PHARMACY	1400 Noriega Street	94122	1	Kiosk Drop-Off Site
SFPD RICHMOND	461 6TH AVE	94118	1	Kiosk Drop-Off Site
ANZA BRANCH LIBRARY	550 - 37th Ave	94121	1	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 14	551 26th Ave	94121	1	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 31	441 12th Ave	94118	1	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 34	499 41st Ave	94121	1	Mail-Back Distribution Location
RICHMOND BRANCH LIBRARY	351 - 9th Avenue	94118	1	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 10	655 Presidio Avenue	94115	2	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 16	2251 Greenwich St	94123	2	Mail-Back Distribution Location
GOLDEN GATE VALLEY BRANCH LIBRARY	1801 Green Street	94123	2	Mail-Back Distribution Location
MARINA BRANCH LIBRARY	1890 Chestnut Street	94123	2	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 38	2150 California St	94115	2	Mail-Back Distribution Location
PRESIDIO BRANCH LIBRARY	3150 Sacramento St	94115	2	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
SAN FRANCISCO FIRE STATION 51	218 Lincoln Blvd	94129	2	Mail-Back Distribution Location
CHINESE HOSPITAL PHARMACY	845 Jackson Street ROOM 1102	94133	3	Kiosk Drop-Off Site
CLAY MEDICAL PHARMACY	929 Clay Street Ste 103	94108	3	Kiosk Drop-Off Site
NORTH EAST MEDICAL SERVICES PHARMACY	1520 Stockton Street	94133	3	Kiosk Drop-Off Site
SFPD CENTRAL	766 VALLEJO ST	94133	3	Kiosk Drop-Off Site
CHINATOWN BRANCH LIBRARY	1135 Powell Street	94108	3	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 13	530 Sansome St	94111	3	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 2	1340 Powell St	94133	3	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 28	1814 Stockton St	94133	3	Mail-Back Distribution Location
NORTH BEACH BRANCH LIBRARY	850 Columbus Avenue	94133	3	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 41	1325 Leavenworth Street	94109	3	Mail-Back Distribution Location
NEMS - CLEMENT PHARMACY	1019 Clement St	94118	4	Kiosk Drop-Off Site
SFPD TARAVAL	2345 24TH ST	94107	4	Kiosk Drop-Off Site
SAN FRANCISCO FIRE STATION 18	1935 32nd Ave	94116	4	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 23	1348 45th Ave	94122	4	Mail-Back Distribution Location
ORTEGA BRANCH LIBRARY	3223 Ortega Street	94122	4	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
PARKSIDE BRANCH LIBRARY	1200 Taraval Street	94116	4	Mail-Back Distribution Location
SUNSET BRANCH	1305 - 18th Avenue	94122	4	Mail-Back Distribution Location
CHARLIES DRUG	1101 Fillmore Street	94115	5	Kiosk Drop-Off Site
KAISER FOUNDATION HEALTH PLAN PHARMACY	2238 Geary Blvd. 1st Floor	94115	5	Kiosk Drop-Off Site
KAISER FOUNDATION HEALTH PLAN PHARMACY	2238 Geary Blvd. 1st Floor	94115	5	Kiosk Drop-Off Site
POST AND DIVISADERO MEDICAL PHARMACY	2299 Post St #109	94115	5	Kiosk Drop-Off Site
RELIABLE REXALL SUNSET PHARMACY	801 Irving St	94122	5	Kiosk Drop-Off Site
SFPD NORTHERN	1125 FILLMORE ST	94115	5	Kiosk Drop-Off Site
SFPD PARK	1899 WALLER ST	94117	5	Kiosk Drop-Off Site
SAN FRANCISCO FIRE STATION 12	1145 Stanyan St	94131	5	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 21	1443 Grove St	94117	5	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 22	1290 16th Ave	94122	5	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 36	109 Oak St	94102	5	Mail-Back Distribution Location
PARK BRANCH LIBRARY	1833 Page Street	94117	5	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 5	1301 Turk Street	94115	5	Mail-Back Distribution Location
WESTERN ADDITION BRANCH LIBRARY	1550 Scott Street	94115	5	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
CBHS PHARMACY SERVICES	1380 Howard St, suite 130	94103	6	Kiosk Drop-Off Site
KAISER PERMANENTE PHARMACY #941	1600 OWENS ST 1ST FLOOR	94158	6	Kiosk Drop-Off Site
SF SHERIFF'S DEPARTMENT	70 Oak Grove St	94107	6	Kiosk Drop-Off Site
SFPD SOUTHERN	1251 3RD ST	94158	6	Kiosk Drop-Off Site
SFPD TENDERLOIN	301 EDDY ST	94102	6	Kiosk Drop-Off Site
SAN FRANCISCO FIRE STATION 1	935 Folsom St	94107	6	Mail-Back Distribution Location
MAIN BRANCH LIBRARY	100 Larking St	94102	6	Mail-Back Distribution Location
MISSION BAY BRANCH LIBRARY	960 4th Street	94158	6	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 3	1067 Post St	94109	6	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 35	Pier 22½ , 399 The Embarcadero	94105	6	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 4	449 Mission Rock St	94158	6	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 48	800 Avenue I, Treasure Island	94130	6	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 8	36 Bluxome Street	94107	6	Mail-Back Distribution Location
STUDENT HEALTH SERV PHCY SF	1600 Holloway Ave	94132	7	Kiosk Drop-Off Site
SAN FRANCISCO FIRE STATION 15	1000 Ocean Ave	94112	7	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 19	390 Buckingham Way	94132	7	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
INGLESIDE BRANCH LIBRARY	1298 Ocean Avenue	94112	7	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 20	285 Olympia Way	94127	7	Mail-Back Distribution Location
MERCED BRANCH LIBRARY	155 Winston Drive	94132	7	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 39	1091 Portola Drive	94127	7	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 40	2155 18th Avenue	94116	7	Mail-Back Distribution Location
WEST PORTAL BRANCH LIBRARY	190 Lenox Way	94127	7	Mail-Back Distribution Location
AIDS HEALTHCARE FOUNDATION DBA AHF PHARMACY	4071 18th St	94114	8	Kiosk Drop-Off Site
SFPD MISSION	630 VALENCIA ST	94110	8	Kiosk Drop-Off Site
SAN FRANCISCO FIRE STATION 11	3880 26th St	94131	8	Mail-Back Distribution Location
EUREKA VALLEY BRANCH LIBRARY	1 Jose Sarria Ct.	94114	8	Mail-Back Distribution Location
GLEN PARK BRANCH LIBRARY	2825 Diamond Street	94131	8	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 24	100 Hoffman Ave	94114	8	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 26	80 Digby St	94131	8	Mail-Back Distribution Location
NOE VALLEY BRANCH LIBRARY	451 Jersey Street	94114	8	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
SAN FRANCISCO FIRE STATION 6	135 Sanchez Street	94114	8	Mail-Back Distribution Location
ALTO PHARMACY	1400 Tennessee St	94107	9	Kiosk Drop-Off Site
MISSION WELLNESS PHARMACY	2424 Mission St	94110	9	Kiosk Drop-Off Site
NEMS - SAN BRUNO PHARMACY	2574 San Bruno Ave	94134	9	Kiosk Drop-Off Site
BERNAL HEIGHTS BRANCH LIBRARY	500 Cortland Avenue	94110	9	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 32	194 Park St	94110	9	Mail-Back Distribution Location
MISSION BRANCH LIBRARY	300 Bartlett Street	94110	9	Mail-Back Distribution Location
PORTOLA BRANCH LIBRARY	380 Bacon Street	94134	9	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 42	2430 San Bruno Avenue	94134	9	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 7	2300 Folsom Street	94110	9	Mail-Back Distribution Location
PC AND MZ SAN FRANCISCO GEN HOSPITAL AND TRAUMA CTR OUTPTPHARMACY	1001 Potrero Ave	94110	10	Kiosk Drop-Off Site
SFPD BAYVIEW	201 WILLIAMS AVE	94124	10	Kiosk Drop-Off Site
VISITACION VALLEY PHARMACY	100 Leland Ave	94134	10	Kiosk Drop-Off Site
BAYVIEW BRANCH LIBRARY	5075 - 3rd Street	94124	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 17	1295 Shafter Ave	94124	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 25	3305 3rd St	94124	10	Mail-Back Distribution Location

SITE NAME	ADDRESS	ZIP CODE	DISTRICT	TYPE
SAN FRANCISCO FIRE STATION 29	299 Vermont St	94103	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 37	798 Wisconsin St	94107	10	Mail-Back Distribution Location
POTRERO BRANCH LIBRARY	1616 - 20th Street	94107	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 44	1298 Girard Street	94134	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 49	1415 Evans Avenue	94124	10	Mail-Back Distribution Location
VISITACION VALLEY BRANCH LIBRARY	201 Leland Avenue	94134	10	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 9	2245 Jerrold Avenue	94124	10	Mail-Back Distribution Location
CENTRAL DRUG STORE	4494 Mission Street	94112	11	Kiosk Drop-Off Site
SFPD INGLESIDE	1 SGT JOHN V YOUNG LN	94112	11	Kiosk Drop-Off Site
EXCELSIOR BRANCH LIBRARY	4400 Mission Street	94112	11	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 33	8 Capital St	94112	11	Mail-Back Distribution Location
OCEAN VIEW BRANCH LIBRARY	345 Randolph Street	94132	11	Mail-Back Distribution Location
SAN FRANCISCO FIRE STATION 43	720 Moscow Street	94112	11	Mail-Back Distribution Location

Appendix D

Potential Additional Kiosk Drop-Off Sites

SITE NAME	ADDRESS	ZIP CODE
3175 PHARMACY	3175 17TH STREET	94110
B & B PHARMACY	1727 FILLMORE STREET	94115
COMMUNITY, A WALGREENS PHARMACY #15296	2262 MARKET ST	94114
COSTCO PHARMACY 144	450 10TH STREET	94103
CVS PHARMACY #2852	731 MARKET ST	94103
CVS/PHARMACY # 10188	499 HAIGHT ST	94117
CVS/PHARMACY # 1983	701 PORTOLA DR	94127
CVS/PHARMACY # 4770	1101 MARKET ST	94103
CVS/PHARMACY #10035	581 MARKET ST	94105
CVS/PHARMACY #10080	1059 HYDE ST	94109
CVS/PHARMACY #10189	1285 SUTTER ST	94109
CVS/PHARMACY #4675	377 32ND AVE	94121
CVS/PHARMACY #7657	351 CALIFORNIA ST	94104
CVS/PHARMACY #7955	2025 VAN NESS AVENUE	94109
FRANKLIN PHARMACY	1508 FRANKLIN STREET	94109
GOOD LIFE RX PHARMACY	731 LARKIN ST	94109
JOE'S PHARMACY	5199 GEARY BLVD	94118
KAISER FDN HSP FRENCH OUT PHY 321	4131 GEARY BLVD STE 101	94118
KAISER FDN HSP INP/OUT HSP PHY 31A 315	2425 GEARY BLVD	94115
KAISER FOUNDATION HEALTH PLAN PHARMACY	2238 GEARY BLVD 6TH FL	94115
KAISER HEALTH PLAN PHARMACY NO 338	2238 GEARY BLVD	94115
KAISER PERMANENTE PHARMACY #329	4131 GEARY BLVD FL 1	94118
KOSHLAND PHARM: CUSTOM COMPOUNDING PHARMACY	301 FOLSOM ST STE B	94105
LC MISSION LLC	2462 MISSION ST	94110
LUCKY PHARMACY #755	1515 SLOAT BLVD	94132

SITE NAME	ADDRESS	ZIP CODE
LUCKY PHARMACY #756	1750 FULTON ST	94117
MISSION NEIGHBORHOOD HLTH CTR PHCY	240 SHOTWELL STREET	94110
MISSION WELLNESS PHARMACY	350 PARNASSUS AVE STE 505	94117
NIMBLE PHARMACY	2200 JERROLD AVE UNIT Q	94124
NORTH EAST MEDICAL SERVICES PHARMACY	1520 STOCKTON ST	94133
PARNASSUS HEIGHTS PHARMACY	350 PARNASSUS AVE #100	94117
PHARMACA INTEGRATIVE PHARMACY INC	925 COLE ST	94117
SAFEWAY PHARMACY #0785	850 LA PLAYA ST	94121
SAFEWAY PHARMACY #0909	730 TARAVAL ST	94116
SAFEWAY PHARMACY #0964	4950 MISSION ST	94112
SAFEWAY PHARMACY #0985	2350 NORIEGA ST	94122
SAFEWAY PHARMACY #0995	1335 WEBSTER ST	94115
SAFEWAY PHARMACY #1490	2300-16TH ST	94103
SAFEWAY PHARMACY #1507	2020 MARKET ST	94114
SAFEWAY PHARMACY #1711	15 MARINA BLVD	94123
SAFEWAY PHARMACY #2606	298 KING STREET	94107
SAFEWAY PHARMACY #2646	735 7TH AVE	94118
SCRIPTSITE PHARMACY	870 MARKET ST, STE 1028	94102
ST MARY'S MEDICAL CENTER CLINIC PHY	2235 HAYES ST	94117
SUTTER PROFESSIONAL PHARMACY	2300 SUTTER ST STE 101	94115
SUTTER PROFESSIONAL PHARMACY	2300 SUTTER ST STE 101	94115
THOUSAND CRANES PHARMACY	1832 BUCHANAN ST STE 203	94115
TORGSYN DISCOUNT PHARMACY	5614 GEARY BOULEVARD	94121
UCSF AMBULATORY CARE CTR OUTPATIENT	505 PARNASSUS AVE RM M39	94143
WALGREENS #00887	1524 POLK STREET	94109
WALGREENS #00890	135 POWELL ST	94102
WALGREENS #00893	1344 STOCKTON_ST	94133
WALGREENS #00896	3601 CALIFORNIA ST	94118
WALGREENS #01054	3398 MISSION ST	94110

SITE NAME	ADDRESS	ZIP CODE
WALGREENS #01109	5260 DIAMOND HEIGHTS BLVD	94131
WALGREENS #01120	4645 MISSION ST	94112
WALGREENS #01126	1979 MISSION STREET	94103
WALGREENS #01241	1201 TARAVAL ST	94116
WALGREENS #01283	500 GEARY ST	94102
WALGREENS #01297	670 FOURTH STREET	94107
WALGREENS #01327	498 CASTRO ST	94114
WALGREENS #01393	1630 OCEAN AVE	94112
WALGREENS #01403	3201 DIVISADERO_ST	94123
WALGREENS #01626	2494 SAN BRUNO AVE	94134
WALGREENS #02005	2550 OCEAN AVE	94132
WALGREENS #02088	1333 CASTRO STREET	94114
WALGREENS #02125	320 BAY ST	94133
WALGREENS #02152	1899 FILLMORE ST	94115
WALGREENS #02153	790 VAN NESS AVE	94102
WALGREENS #02244	3801 3RD STREET SUITE 550	94124
WALGREENS #02521	300 MONTGOMERY	94104
WALGREENS #02705	2050 IRVING ST	94122
WALGREENS #02866	1363 DIVISADERO ST	94115
WALGREENS #03185	825 MARKET STREET	94103
WALGREENS #03358	1301 FRANKLIN ST	94109
WALGREENS #03383	141 KEARNY ST	94108
WALGREENS #03475	25 POINT LOBOS AVE	94121
WALGREENS #03624	275 SACRAMENTO ST	94111
WALGREENS #03706	3838 CALIFORNIA ST	94118
WALGREENS #03707	2100 WEBSTER ST SUITE 105	94115
WALGREENS #03711	1189 POTRERO AVE	94110
WALGREENS #03849	745 CLEMENT ST	94118
WALGREENS #03869	1750 NORIEGA ST	94122
WALGREENS #04231	2690 MISSION ST	94110
WALGREENS #04275	456 MISSION STREET	94105
WALGREENS #04318	4129 18TH STREET	94114

SITE NAME	ADDRESS	ZIP CODE
WALGREENS #04492	33 DRUMM ST	94111
WALGREENS #04529	2145 MARKET STREET	94114
WALGREENS #04558	300 GOUGH STREET	94102
WALGREENS #04570	3001 TARAVAL STREET	94116
WALGREENS #04609	1301 MARKET STREET	94103
WALGREENS #04680	730 MARKET STREET	94102
WALGREENS #05487	5300 3RD STREET	94124
WALGREENS #05599	2120 POLK STREET	94109
WALGREENS #06291	116 NEW MONTGOMERY ST	94105
WALGREENS #06557	199 PARNASSUS AVE	94117
WALGREENS #06625	2141 CHESTNUT STREET	94123
WALGREENS #07043	459 POWELL ST	94102
WALGREENS #07044	88 SPEAR STREET	94105
WALGREENS #07150	965 GENEVA AVE	94112
WALGREENS #09886	3400 CESAR CHAVEZ	94110
WALGREENS #10044	45 CASTRO ST SUITE 124	94114
WALGREENS #11385	1580 VALENCIA ST SUITE 101	94110
WALGREENS #13583	901 HYDE ST	94109
WALGREENS #13666	1300 BUSH ST	94109
WALGREENS #13667	5280 GEARY BLVD	94118
WALGREENS #13668	1496 MARKET ST	94102
WALGREENS #13670	200 WEST PORTAL AVE	94127
WALGREENS #15127	1175 COLUMBUS AVE	94133
WALGREENS #15331	500 PARNASSUS AVE J LEVEL ROOM MU-145	94143
WALGREENS #16373	550 16TH STREET	94158
WELLMAN'S PHARMACY	1053 STOCKTON STREET	94108
WELLMAN'S PHARMACY	728 PACIFIC AVENUE #110	94133

Appendix E¹

Kiosk Prototype and Proposed Signage



¹ If the General Public Fact Sheet is modified to allow for commingling of inhalers and/or iodine-containing medications with controlled substances, MED-Project will accept inhalers and/or iodine-containing medications in collection receptacles and modify front panel kiosk art signage accordingly.

Proposed Kiosk Signage

Front Panel Door Kiosk Art

MEDICINE DISPOSAL

ELIMINACIÓN DE MEDICAMENTOS 用药处理

PAGTATAPON NG GAMOT
Утилизация медицинских препаратов

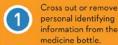
SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

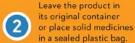












If transferring medications to a sealed bag, please be sure to recycle all remaining packaging.



Put medicine in the kiosk.



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



NOT ACCEPTED: HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, INHALERS, MEDICAL DEVICES, SHARPS, ILLICIT DRUGS, IODINE-CONTAINING MEDICATIONS.

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, may expose you to chemicals known to the State of California to cause cancer, birth defects, reproductive toxicity and/or other reproductive harm.

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



Proposed Kiosk Signage

Side Panel Kiosk Art

MEDICINE DISPOSAL

ELIMINACIÓN DE MEDICAMENTOS • PAGTATAPON NG GAMOT 用药处理 • Утилизация медицинских препаратов

SAFELY DISPOSE OF UNWANTED & EXPIRED MEDICINES

MED-Project

Medication Education & Disposal

Proposed Kiosk Signage

Front Panel Drop-Slot Kiosk Art



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



NOT ACCEPTED: HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, INHALERS, MEDICAL DEVICES, SHARPS, ILLICIT DRUGS, IODINE-CONTAINING MEDICATIONS.

Name: 123 Pharmacy

Contact: **(555) 555-5555**





UNWANTED MEDICINE



INJECTORS



IODINE-CONTAINING MEDICATIONS



INHALERS

For more information, please visit www.MED-Project.org or call 1-844-MED-Project

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

Appendix F

Sample Media List

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

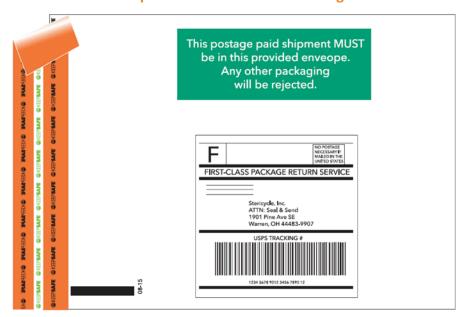
Print Outlets	Coverage Area	Website
Bay Area Reporter	San Francisco	http://www.ebar.com
El Tecolote (Spanish/English)	San Francisco	http://eltecolote.org/content/en/
Golden Gate Xpress (University)	San Francisco	http://goldengatexpress.org
Jewish Bulletin	San Francisco	http://www.jweekly.com
Korea Daily	San Francisco	http://www.koreadaily.com/index_local_branch.html?branch=SF
Marina Times	San Francisco	http://www.marinatimes.com
New Fillmore	San Francisco	http://newfillmore.com
Nichi Bei Times (Japanese/English)	San Francisco	http://www.nichibei.org
Nob Hill Gazette	San Francisco	http://nobhillgazette.com/preview/
San Francisco Bay Guardian	San Francisco	http://www.sfbg.com
San Francisco Bay View	San Francisco	http://sfbayview.com
San Francisco Business Times	San Francisco	http://www.bizjournals.com/sanfrancisco/news/
San Francisco Chronicle	San Francisco	http://www.sfgate.com
San Francisco Examiner	San Francisco	http://www.sfexaminer.com
San Francisco Foghorn (University)	San Francisco	http://sffoghorn.org
San Francisco Frontlines	San Francisco	http://www.sf-frontlines.com
SF Weekly	San Francisco	http://www.sfweekly.com

Sing Tao Daily (Chinese)	San Francisco	https://www.singtaousa.com/?variant=zh-hk&fs=16
Synapse (University)	San Francisco	http://synapse.ucsf.edu
The Epoch Times (Chinese/English)	San Francisco	http://www.theepochtimes.com
The Guardsman (University)	San Francisco	http://theguardsman.com
The Independent	San Francisco	http://www.theindependentsf.com
The Korean Times	San Francisco	http://sf.koreatimes.com
The Noe Valley Voice	San Francisco	http://www.noevalleyvoice.com/2016/April/index.html
The Potrero View	San Francisco	http://www.potreroview.net
World Journal (Chinese)	San Francisco	http://www.worldjournal.com

Television Outlets	Network
BAVC	Public Access
KDTV	Univision
KEMO	Azteca America
KGO	ABC
KNTV	NBC
KPIX	CBS
KQED	PBS
KRON	Media General
KSTS	Telemundo
KTVU	FOX
Radio Outlets	Coverage Area
KALW FM 91.7	San Francisco
KCBS AM 740	San Francisco
KCSF (College app radio)	San Francisco
KGO AM 810	San Francisco
KQED FM 88.5	San Francisco
KSFO AM 560	San Francisco
KUSF (College online radio)	San Francisco

Appendix G¹

Sample Standard Mail-Back Package



Description:

Plastic envelope with return label and instructional flyer

Package Size:

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

melt tape,

Return label: 4" x 4"

Instructional sheet: 5" x 7"

Paper Stock:

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

Return label: 60# uncoated label stock

Instructional sheet: 80# gloss text

Color:

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

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

Instructional sheet: K/K

MED-Project may choose to change its Vendor for Mail-Back Services at any time, in accordance with Ordinance and Regulation requirements.

¹ If the General Public Fact Sheet is modified to allow for commingling iodine-containing medications with controlled substances, MED-Project will accept iodine-containing medications in collection receptacles, and will discontinue Mail-Back Services for iodine-containing medications (except for certain services required pursuant to Ordinance § 2205(b)(5)).

Appendix H

Sample Injector Mail-Back Package



Description:

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

Package Sizes:

1.4 quart mail-back system

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

MED-Project may choose to change its Vendor for Mail-Back Services at any time, in accordance with Ordinance and Regulation requirements.

Appendix I¹

Sample Inhaler Mail-Back Package Description

Description:

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

Package Sizes:

1.4 quart to 2.5 gallon mail-back system

Mail-back solutions are an example of complete, turnkey systems to provide for the safe return of inhaler waste through the United States Postal Service. Mail-back solutions are tested and permitted to USPS specifications as outlined in USPS Publication 52.

MED-Project may choose to change its Vendor for Mail-Back Services at any time, in accordance with Ordinance and Regulation requirements.

¹ If the General Public Fact Sheet is modified to allow for commingling inhalers with controlled substances, MED-Project will accept inhalers in collection receptacles, and will discontinue Mail-Back Services for inhalers (except for certain services required pursuant to Ordinance § 2205(b)(5)).

Appendix J

Request for Approval of Standard Mail-Back Package Disposal Process

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



May 31, 2018

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

Pursuant to § 2211(f) of the San Francisco Safe Drug Disposal Stewardship Ordinance, codified at Chapter 22, Division I of the San Francisco Environment Code ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Department of the Environment (the "Director") to use a permitted medical waste incinerator for the disposal of Standard Mail-Back Packages for unwanted medicine. As described below, exercising discretion to allow for the disposal of Standard Mail-Back Packages at a permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 2211(f) of the Ordinance. Further, because cost, logistics, and other considerations make disposal of Standard Mail-Back Packages at permitted hazardous waste facilities not feasible at this time, approving the disposal of Standard Mail-Back Packages at a permitted medical waste incinerator would be consistent with the intent of Ordinance § 2207(b).

I. THE PROCESS FOR THE DISPOSAL OF STANDARD MAIL-BACK PACKAGES AT THE WARREN INCINERATOR

MED-Project is proposing to continue to provide Standard Mail-Back Packages that are pre-addressed and pre-paid for delivery to the Stericycle, Inc. ("Stericycle") incinerator in Warren, Ohio (the "Warren Incinerator")² for destruction via incineration. The Warren Incinerator will scan the unique identifier on each Standard Mail-Back Package to record receipt of the package before incinerating it, and will confirm the materials have been properly incinerated.

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

The Warren Incinerator is a United States Drug Enforcement Administration ("DEA") registered collector facility and destroys Standard Mail-Back Packages from MED-Project and other Stericycle clients in compliance with DEA requirements.

The Warren Incinerator facility registration and permit numbers along with 5-year penalty records are available upon request.

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

In approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance under § 2211(f) in order to achieve the objectives of the Ordinance, which include protecting and providing for the environment and public health, safety, and welfare in San Francisco. *See* Ordinance § 2201.

Additionally, under the Ordinance § 2207(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including those collected in Standard Mail-Back Packages, at a permitted large municipal waste combustor, as defined by the United States Environmental

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

Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

III. THE USE OF THE WARREN INCINERATOR TO DISPOSE OF STANDARD MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE §§ 2211(f) and 2207(b) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of the Warren Incinerator for disposal of Standard Mail-Back Packages under Ordinance § 2211(f) because disposal at the Warren Incinerator would protect and provide for the environment and the health, safety, and welfare of the public, as discussed further below, in furtherance of the objectives of the Ordinance. Furthermore, the Director should also exercise its discretion to approve incineration of Standard Mail-Back Packages at the Warren Incinerator since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations, consistent with the intent of Ordinance § 2207(b).

A. <u>Disposal at the Warren Incinerator would protect and provide for the environment and the health,</u> safety, and welfare of the public.

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

As these applicable requirements protect and provide for the environment and the health, safety, and welfare of the general public, the Director should exercise its discretion under Ordinance § 2211(f) to approve the Warren Incinerator as a disposal site for Standard Mail-Back Packages. Such approval would be consistent with the intent of Ordinance § 2207(b) to allow other disposal options should hazardous waste disposal facilities prove not feasible.

B. <u>Disposal of Standard Mail-Back Packages at a Permitted Hazardous Waste Facility is Not Feasible.</u>

MED-Project requests approval to use the Warren Incinerator because disposal of Standard Mail-Back Packages at the previously approved Stericycle, Inc., Indianapolis, Indiana facility or permitted hazardous waste disposal facilities is not feasible at this time due to logistics, cost, and other considerations.

First, MED-Project's vendor for Standard Mail-Back Packages, Stericycle, has changed its offerings and discontinued operation of the mail-back envelope destruction process at the Stericycle, Inc., Indianapolis, Indiana facility that MED-Project previously relied on to provide these services. Stericycle now only offers disposal at the Warren Incinerator for the Standard Mail-Back Packages distributed by MED-Project. The process offered for disposal at the Warren Incinerator is efficient and simple, as Standard Mail-Back Packages are shipped to the ultimate disposal facility and incinerated onsite. MED-Project will be considering alternative disposal options, but the use of a hazardous waste disposal facility for Standard Mail-Back Packages is not logistically feasible at present given the information MED-Project has received from its vendor about the vendor's access to disposal facilities.

Second, the cost to dispose of Standard Mail-Back Packages at a hazardous waste disposal facility, if any DEA registered collector hazardous waste disposal facilities exist, would be much greater than the cost to dispose of such packages at the Warren Incinerator. In MED-Project's experience, hazardous waste

incinerators typically charge significantly more than medical waste incinerators to dispose of the same quantity of waste. Additionally, identifying a hazardous waste disposal facility willing and able to accept Standard Mail-Back Packages, if any such facilities exist, would cause delay in service to the public and increase MED-Project's costs, further supporting the conclusion that it is infeasible from both a cost and logistics standpoint for MED-Project to dispose of Standard Mail-Back Packages at a hazardous waste incinerator.

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

For the above reasons, the use of the Warren Incinerator to dispose of Standard Mail-Back Packages would meet the standard at Ordinance § 2207(b), under which the Director can approve disposal at a municipal waste combustor. Disposal at the Warren Incinerator is at least as protective of the environment and human health as compared to a municipal waste combustor. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 2207(b), but not at a medical waste incinerator (i.e., the Warren Incinerator) that is permitted to receive this waste and would protect and provide for the environment and the health, safety, and welfare of the public. Accordingly, MED-Project requests that the Director approve disposal of Standard Mail-Back Packages at the Warren Incinerator.

IV. CONCLUSION

Accordingly, the Director should approve the disposal of Standard Mail-Back Packages via incineration at the Warren Incinerator as proposed by MED-Project under Ordinance § 2211(f) and consistent with the intent of Ordinance § 2207(b).

Appendix K

Request for Approval of Injector Mail-Back Package Disposal Process

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



May 31, 2018

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

Pursuant to § 2211(f) and § 2207(b) of the San Francisco Safe Drug Disposal Stewardship Ordinance, codified at Chapter 22 of the San Francisco Environment Code ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Department of the Environment (the "Director") to use permitted municipal waste combustors and a permitted medical waste incinerator for the disposal of Injector Mail-Back Packages (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, exercising discretion to allow for the disposal of Injector Mail-Back Packages at a permitted municipal waste combustor or permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 2211(f) of the Ordinance. Further, cost, logistics, and other considerations make disposal of Injector Mail-Back Packages at permitted hazardous waste facilities not feasible at this time.

I. THE PROCESS FOR THE DISPOSAL OF INJECTOR MAIL-BACK PACKAGES AT THE PROPOSED INCINERATORS

MED-Project is proposing that Injector Mail-Back Packages will be pre-addressed and pre-paid for delivery to the Daniels Sharpsmart facility in Fresno, California (the "Daniels Facility"), for transport to one of three incinerators for disposal: the Covanta Huntsville, Inc. facility (the "Covanta Huntsville Facility")³; the Covanta Marion, Inc. facility (the "Covanta Marion Facility")⁴; or the Healthcare Environmental Services, LLC's Fargo Facility (the "HESI Facility").⁵ The Daniels Facility will scan the unique identifier on each Injector Mail-Back Package to record receipt of the package before sending it for incineration to one of these three facilities. These facilities will receive and dispose of the Injector Mail-Back Packages, and provide confirmation that the materials have been properly incinerated and disposed of.

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

A. Covanta Huntsville Facility

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

³ Covanta Huntsville's mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.

⁴ Covanta Marion's mailing address is 4850 Brooklake Road, NE, Brooks, OR 97305.

⁵ The HESI Facility's mailing address is 1420 40th Street North, Fargo, ND 58102.

⁶ See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, http://swdahsv.org/waste-to-energy/.

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

⁸ Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all about vpp.html.

B. Covanta Marion Facility

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

C. HESI Facility

MED-Project is also requesting approval to dispose of Injector Mail-Back Packages at the HESI Facility, which is a permitted hospital, medical, and infectious waste incinerator. The HESI Facility operates a multiple chamber incinerator approximately 50 weeks per year on a 24-hour basis with the capacity to incinerate 1,200 pounds per hour. ¹³ To control air pollution, the HESI Facility relies on a multiple chamber incinerator utilizing a sodium bi-carbonate-injection dry scrubber/baghouse system. ¹⁴ The HESI facility is permitted to treat medical wastes, including sharps, and certain other wastes, including expired and unused pharmaceuticals. ¹⁵

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

In approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance in order to achieve the objectives of the Ordinance, which include protecting and preserving the environment and public health, safety and welfare in San Francisco. *See* Ordinance § 2201.

Additionally, under the Ordinance § 2207(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including injectors, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

III. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INJECTOR MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 2211(f) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of all three proposed incinerators for disposal of Injector Mail-Back Packages under Ordinance § 2211(f) because disposal at the proposed incinerators would protect and provide for the environment and the health, safety, and welfare of the public, as discussed further below, in furtherance of the objectives of the Ordinance. Furthermore, as explained in section IV below, the Director should also exercise its discretion to approve these alternative incineration methods since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations.

D. Covanta Huntsville Facility and Covanta Marion Facility

Disposal of Injector Mail-Back Packages at the Covanta Huntsville Facility and Covanta Marion Facility would provide for and protect the environment and the health, safety, and welfare of the general public. In

⁹ See Covanta, Covanta Marion, https://www.covanta.com/Our-Facilities/Covanta-Marion.

 $^{^{10}}$ *Id*.

¹¹ Id

¹² Id.; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all about vpp.html.

¹³ See HESI, Biomedical Waste, http://hesiservices.com/our-servces/biomedical-waste/.

¹⁴ See HESI Facility's Title V Permit To Operate No. T5-178001 § 1.

¹⁵ See HESI Facility's Solid Waste Management Facility Permit No. ITF-0203 § II.C.

particular, these facilities have extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. They have also been recognized for their workplace safety achievements, as evidenced by their status as VPP Star facilities.

E. HESI Facility

Disposal of Injector Mail-Back Packages at the HESI Facility would also protect and provide for the environment and the health, safety, and welfare of the general public, like the municipal waste combustors. Medical waste incinerators, like the HESI Facility, are typically subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The HESI Facility is subject to environmental permits, including a Title V permit for air emissions and a state solid waste management permit, and the facility employs air pollution controls, including a sodium bi-carbonate-injection dry scrubber/baghouse system. The facility's Title V air permit cites to federal standards and emissions limits that are specific to incinerators for hospital, medical, and infectious waste. Additionally, facilities that handle medical waste, like the HESI Facility, are subject to a suite of worker health and safety standards. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

Finally, the Director should also exercise its discretion under Ordinance § 2211(f) to approve the HESI Facility since disposal at a hazardous waste facility is not feasible at this time due to logistics, cost, and other considerations, as described in the following section IV.

IV. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INJECTOR MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 2207(b) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

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

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

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

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

For the above reasons, the Director should approve MED-Project's request to use the Covanta Huntsville Facility and Covanta Marion Facility to dispose of Injector Mail-Back Packages under Ordinance § 2207(b).

Additionally, the use of the HESI Facility to dispose of Injector Mail-Back Packages would meet the same standard. Disposal at the HESI Facility is at least as protective of the environment and human health, as compared to a municipal waste combustor. *See* sections II and III above. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 2207(b), but not at a medical waste facility (i.e., the HESI Facility) that is permitted to receive this waste and would provide for and protect the environment and the health, safety, and welfare of the public. Accordingly, MED-Project requests that the Director approve disposal of Injector Mail-Back Packages at the HESI Facility.

V. CONCLUSION

Accordingly, the Director should approve the disposal of Injector Mail-Back Packages via incineration at the Covanta Huntsville Facility, the Covanta Marion Facility, and the HESI Facility as proposed by MED-Project under Ordinance § 2207(b) and § 2211(f).

Appendix L

Request for Approval of Inhaler Mail-Back Package Disposal Process

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



May 31, 2018

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

Pursuant to § 2211(f) and § 2207(b) of the San Francisco Safe Drug Disposal Stewardship Ordinance, codified at Chapter 22 of the San Francisco Environment Code ("Ordinance"), MED-Project LLC ("MED-Project") requests approval from the Director of the Department of the Environment (the "Director") to use permitted municipal waste combustors and a permitted medical waste incinerator for the disposal of Inhaler Mail-Back Packages (as defined in the MED-Project Product Stewardship Plan ("Plan") § III). As described below, exercising discretion to allow for the disposal of Inhaler Mail-Back Packages at a permitted municipal waste combustor or permitted medical waste incinerator would achieve the objectives of the Ordinance in accordance with § 2211(f) of the Ordinance. Further, cost, logistics, and other considerations make disposal of Inhaler Mail-Back Packages at permitted hazardous waste facilities not feasible at this time.

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

MED-Project is proposing that Inhaler Mail-Back Packages will be pre-addressed and pre-paid for delivery to the Daniels Sharpsmart facility in Fresno, California (the "Daniels Facility"), for transport to one of three incinerators for disposal: the Covanta Huntsville, Inc. facility (the "Covanta Huntsville Facility")¹⁶; the Covanta Marion, Inc. facility (the "Covanta Marion Facility")¹⁷; or the Healthcare Environmental Services, LLC's Fargo Facility (the "HESI Facility").¹⁸ The Daniels Facility will scan the unique identifier on each Inhaler Mail-Back Package to record receipt of the package before sending it for incineration to one of these three facilities. These facilities will receive and dispose of the Inhaler Mail-Back Packages, and provide confirmation that the materials have been properly incinerated and disposed of.

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

A. Covanta Huntsville Facility

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

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¹⁶ Covanta Huntsville's mailing address is 5251 Triana Blvd SW, Huntsville, AL 35805.

¹⁷ Covanta Marion's mailing address is 4850 Brooklake Road, NE, Brooks, OR 97305.

¹⁸ The HESI Facility's mailing address is 1420 40th Street North, Fargo, ND 58102.

¹⁹ See Solid Waste Disposal Authority of the City of Huntsville, Waste to Energy, http://swdahsv.org/waste-to-energy/.

²⁰ See Covanta, Covanta Huntsville, https://www.covanta.com/Our-Facilities/Covanta-Huntsville.

²¹ *Id.*; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

B. Covanta Marion Facility

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

C. HESI Facility

MED-Project is also requesting approval to dispose of Inhaler Mail-Back Packages at the HESI Facility, which is a permitted hospital, medical, and infectious waste incinerator. The HESI Facility operates a multiple chamber incinerator approximately 50 weeks per year on a 24-hour basis with the capacity to incinerate 1,200 pounds per hour. To control air pollution, the HESI Facility relies on a multiple chamber incinerator utilizing a sodium bi-carbonate-injection dry scrubber/baghouse system. The HESI facility is permitted to treat medical wastes and certain other wastes, including expired and unused pharmaceuticals.

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

In approving a plan, the Director has discretion to waive strict compliance with the requirements of the Ordinance in order to achieve the objectives of the Ordinance, which include protecting and preserving the environment and public health, safety and welfare in San Francisco. *See* Ordinance § 2201.

Additionally, under the Ordinance § 2207(b), the Director may grant approval for a stewardship plan to dispose of some, or all, of the collected covered drugs, including inhalers, at a permitted large municipal waste combustor, as defined by the United States Environmental Protection Agency under 40 C.F.R. parts 60 and 62, if use of a hazardous waste disposal facility is not feasible based on cost, logistics or other considerations.

III. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 2211(f) TO ACHIEVE THE OBJECTIVES OF THE ORDINANCE

The Director should exercise its discretion and approve the use of all three proposed incinerators for disposal of Inhaler Mail-Back Packages under Ordinance § 2211(f) because disposal at the proposed incinerators would protect and provide for the environment and the health, safety, and welfare of the public, as discussed further below, in furtherance of the objectives of the Ordinance. Furthermore, as explained in section IV below, the Director should also exercise its discretion to approve these alternative incineration methods since disposal at a hazardous waste facility is not feasible based on logistics, cost, and other considerations.

A. Covanta Huntsville Facility and Covanta Marion Facility

Disposal of Inhaler Mail-Back Packages at the Covanta Huntsville Facility and Covanta Marion Facility would provide for and protect the environment and the health, safety, and welfare of the general public. In

²² See Covanta, Covanta Marion, https://www.covanta.com/Our-Facilities/Covanta-Marion.

 $^{^{23}}$ *Id*.

²⁴ *Id*.

²⁵ *Id.*; U.S. Occupational Health and Safety Administration, All About VPP, https://www.osha.gov/dcsp/vpp/all_about_vpp.html.

²⁶ See HESI, Biomedical Waste, http://hesiservices.com/our-servces/biomedical-waste/.

²⁷ See HESI Facility's Title V Permit To Operate No. T5-178001 § 1.

²⁸ See HESI Facility's Solid Waste Management Facility Permit No. ITF-0203 § II.C.

particular, these facilities have extensive pollution control technologies in place, including semi-dry flue gas scrubbers injecting lime, fabric filter baghouses, a nitrogen oxide control system, a mercury control system, and a continuous emissions monitoring system. They have also been recognized for their workplace safety achievements, as evidenced by their status as VPP Star facilities.

B. HESI Facility

Disposal of Inhaler Mail-Back Packages at the HESI Facility would also protect and provide for the environment and the health, safety, and welfare of the general public, like the municipal waste combustors. Medical waste incinerators, like the HESI Facility, are typically subject to stringent environmental requirements, as well as worker health and safety standards like other incinerators. The HESI Facility is subject to environmental permits, including a Title V permit for air emissions and a state solid waste management permit, and the facility employs air pollution controls, including a sodium bi-carbonate-injection dry scrubber/baghouse system. The facility's Title V air permit cites to federal standards and emissions limits that are specific to incinerators for hospital, medical, and infectious waste. Additionally, facilities that handle medical waste, like the HESI Facility, are subject to a suite of worker health and safety standards that would not otherwise be in place. These requirements typically range from the use of personal protective equipment to specific handling and containment procedures.

Finally, the Director should also exercise its discretion under Ordinance § 2211(f) to approve the HESI Facility since disposal at a hazardous waste facility is not feasible at this time due to logistics, cost, and other considerations, as described in the following section IV.

IV. THE USE OF THE PROPOSED INCINERATORS TO DISPOSE OF INHALER MAIL-BACK PACKAGES SHOULD BE APPROVED UNDER ORDINANCE § 2207(b) BECAUSE DISPOSAL AT A PERMITTED HAZARDOUS WASTE FACILITY IS NOT FEASIBLE

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

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

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

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

For the above reasons, the Director should approve MED-Project's request to use the Covanta Huntsville Facility and Covanta Marion Facility to dispose of Inhaler Mail-Back Packages under Ordinance § 2207(b).

Additionally, the use of the HESI Facility to dispose of Inhaler Mail-Back Packages would meet the same standard. Disposal at the HESI Facility is at least as protective of the environment and human health, as compared to a municipal waste combustor. *See* sections II and III above. MED-Project sees no reason that the Ordinance would allow disposal at a municipal waste combustor under Ordinance § 2207(b), but not at a medical waste facility (i.e., the HESI Facility) that is permitted to receive this waste and would provide for and protect the environment and the health, safety, and welfare of the public. Accordingly, MED-Project requests that the Director approve disposal of Inhaler Mail-Back Packages at the HESI Facility.

V. CONCLUSION

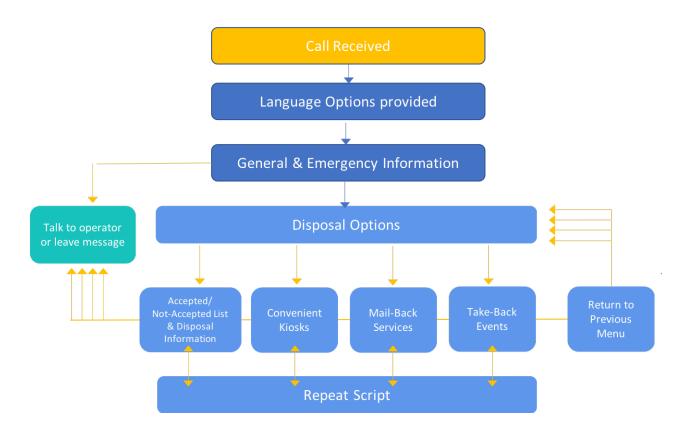
Accordingly, the Director should approve the disposal of Inhaler Mail-Back Packages via incineration at the Covanta Huntsville Facility, the Covanta Marion Facility, and the HESI Facility as proposed by MED-Project under Ordinance § 2207(b) and § 2211(f).

Appendix M

Sample Call Center Script

MED-Project Medication Education & Disposal

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



Call Script:

- If you are experiencing a medical emergency, please hang up and dial 9-1-1.
- If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call California Poison Control at 800-222-1222.
- Kiosks are located throughout the County and provide convenient options for returning expired or unwanted medicine. <u>Press 3</u> for more information about convenient kiosks.
- Take-Back Events may be available in your area. Press 4 for more information.
- Mail-Back Services are available to Residents. <u>Press 5</u> for more information.
- You may <u>press 0</u> at any time to speak with an operator about disposal options.
- MED-Project is a consumer education campaign dedicated to proper medication use and consumer disposal.

- MED-Project reminds you that taking your medicine as directed by your health care provider is critically important to your health.
- If you have questions about your medication, please hang up and dial your health care provider.
- For additional questions about the proper disposal of expired or Unwanted Medicine from households, please go to <u>MEDProject.org</u> or <u>press 0</u> to talk to an operator.
- To hear this menu again, please press 1.
- Thank you for calling MED-Project.

Kiosk Script for when 3 is selected:

- Kiosks to collect expired and Unwanted Medicine are located throughout your local area. To locate the kiosk site nearest you, or for precise information about kiosk site contact information, press 0 to speak with an operator or visit <u>MEDProject.org</u> to search by your zip code. Mail-Back Distribution Locations may also be available in your area.
- Kiosks accept medications in any dosage form in their original container or sealed bag. For iodine-containing medications, inhalers or Pre-filled Injector Products, please <u>press 5</u> or talk to an operator. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; medical devices; sharps; or illicit drugs will be accepted.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 3.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

Take-back Script for when 4 is selected:

- MED-Project is working with local law enforcement and household hazardous waste facilities to offer Take-Back Events for the collection of Unwanted Medicines from Residents. For a complete list of Take-Back Events, please <u>press 0</u> to speak to the operator or visit MEDProject.org.
- Medications in any dosage form in their original container or sealed bag are
 accepted at Take-Back Events. For iodine-containing medications, inhalers or Prefilled Injector Products, please <u>press 5</u> or talk to an operator. No herbal remedies,
 vitamins, supplements, cosmetics or other personal care products; medical devices;
 sharps; or illicit drugs will be accepted.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 4.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

Mail-Back Services²⁹ Script for when 5 is selected:

- Mail-Back Services are available to Residents who are disabled and home-bound or home healthcare professionals providing services to disabled and home-bound Residents. Mail-Back Services are also available to all Residents for Pre-filled Injector Products, inhalers, and iodine-containing medications.
- Mail-Back Distribution Locations may also be available near you.
- To request a mail-back package, please press 0 to talk to the operator or visit MEDProject.org.
- Mail-back packages accept medications in any dosage form in their original container or sealed bag. No herbal remedies, vitamins, supplements, cosmetics or other personal care products; medical devices; sharps; or illicit drugs will be accepted.
- If you do transfer your medications to a sealed bag, please be sure to recycle all remaining packaging.
- To protect your privacy, remove or black out all personally identifiable information before disposing of your medications or recycling your drug packaging.
- To repeat this information, press 5.
- To return to the main menu, please press 1.
- Thank you for calling MED-Project.

²⁹ Mail-back package dimensions or capacity will be included in the final call script that is published to the IVR.

Appendix N

MED-Project Website



Medication Education & Disposal









San Francisco City and County, CA

Medicines help treat diseases, manage chronic conditions, and improve health and well-being for millions of Americans. It's vitally important that patients take their medicines as prescribed by their health care provider. However, if you have expired or unwanted medication, proper disposal is important and easy.



查看本页面(中文)

Просмотреть страницу на русском языке

Ver esta página en español

Tingnan ang page na ito sa Tagalog

CLICK ON ANY OF THE RECOMMENDED DISPOSAL OPTIONS BELOW TO LEARN MORE







CONVENIENT KIOSKS



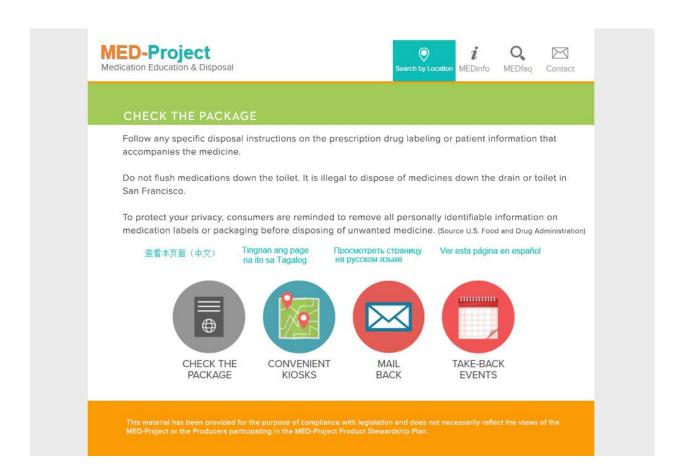
MAIL BACK



TAKE-BACK **EVENTS**

In accordance with the San Francisco Department of the Environment Regulation, the disposal of Unwanted Medicine in any refuse collection container, including a collections cart, receptacle, bin, or debris box, is discouraged.

Proposed Web Page



Proposed Web Page











CONVENIENT KIOSKS

Community drug take-back locations at law enforcement agencies and pharmacies allow residents to bring expired or unwanted medicines to a convenient, centralized location for proper disposal. Residents may also go to selected locations to request a mail-back package for expired or unwanted medicines.

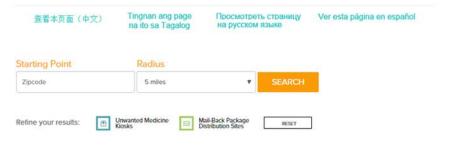
MATERIALS ACCEPTED IN UNWANTED MEDICINE KIOSKS

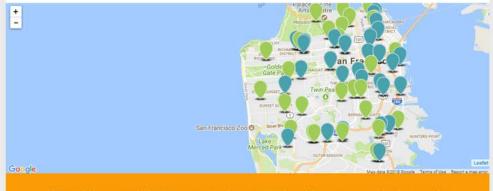
ACCEPTED: Medications in any dosage form, except for those listed below, in their original container or sealed bag.*

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

NOT ACCEPTED: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, medical devices, sharps, illicit drugs and iodine-containing medications.

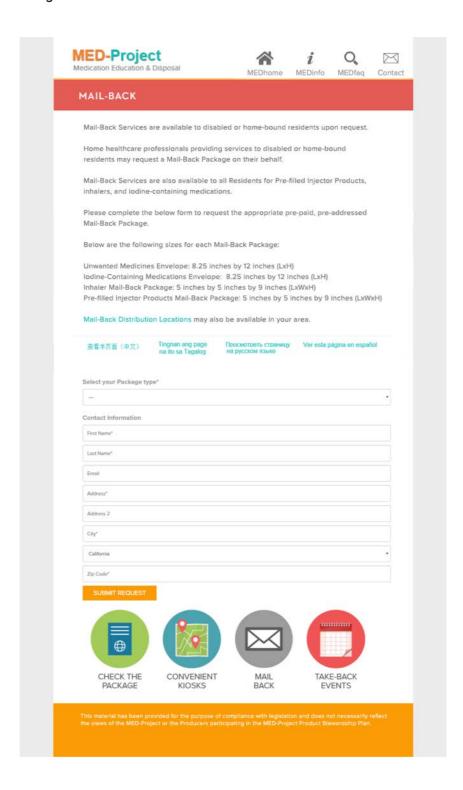
To find the nearest disposal or mail-back distribution locations, enter your zip code below.





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

Proposed Web Page¹



¹ Mail-back package dimensions or capacity will be included in the final web page that is published to the MED-Project Website.

Proposed Web Page











MEDinfo

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

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

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

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English	Cililese	Russiali	Spanish	lagalog
Frequently As	ked Questions:			
English	Chinese	Russian	Spanish	Tagalog
Mail-Back Pac	kage Insert:			
English	Chinese	Russian	Spanish	Tagalog

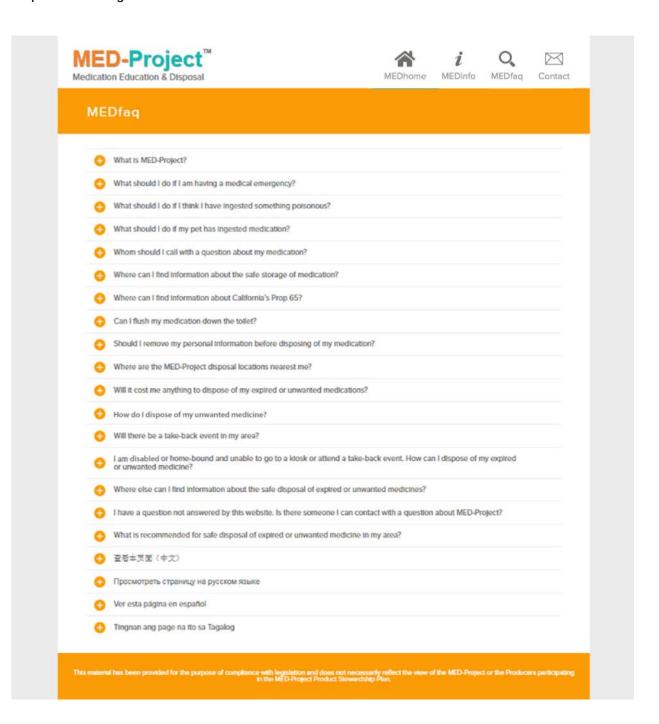
Survey Information & Results:

Survey Results 2018

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

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

Proposed Web Page



Proposed Web Page











If you are experiencing a medical emergency, please dial 9-1-1. If you are experiencing a non-emergency but suspect that you or a family member has ingested something poisonous, please call Poison Control at 800-222-1222. If you have questions about your medication, please dial your health care provider.

查看本页面(中文)

Tingnan ang page na ito sa Tagalog Просмотреть страницу на русском языке Ver esta página en español For answers to some frequently asked questions about MED-Project, click here.

Residents

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

1-(844)-MED-PROJ or 1-(844) 633-7765

Pharmacies and Law Enforcement Offices

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

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

Drug Producers

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

Phone: (202) 495-3131 Email: compliance@med-project.org

Appendix O

Sample Brochure and Mail-Back Inserts

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

Front of brochure

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

MED-Project Medication Education & Disposal

www.med-project.org/SF or call 1-844-MED-PROJ

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's vitally important that patients take their medicine as prescribed by their health care provider and as indicated on the label or packaging. It's also important to be sure to store medications securely to prevent accidental ingestion or misuse by others in your household, especially children.

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

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



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









In accordance with the San Francisco Department of the Environment Regulation, the disposal of Unwanted Medicine in any refuse collection container, including a collection cart, receptacle, bin, or debris box, is discouraged.

MED-Project Medication Education & Disposal www.med-project.org/SF

DISPOSAL OPTIONS

CHECK THE PACKAGE



If there are specific instructions for disposal on the label, package or package insert, please follow those instructions. Do not flush medications down the toilet. It is illegal to dispose of medicines down the drain or toilet in San Francisco.

CONVENIENT KIOSKS



To find convenient kiosks in your area, visit www.med-project.org/SF for more information. Mail-back package distribution locations may also be available in your area.

What items can I dispose of?



ACCEPTED:

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

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



NOT ACCEPTED:

HERBAL REMEDIES, VITAMINS, SUPPLEMENTS, COSMETICS, OTHER PERSONAL CARE PRODUCTS, COMPRESSED CYLINDERS, AEROSOLS, INHALERS, MEDICAL DEVICES, SHARPS, ILLICIT DRUGS, IODINE-CONTAINING MEDICATIONS.

DISPOSAL OPTIONS

MAIL-BACK



Mail-Back Services for unwanted medicine are available to differentiallyabled or home-bound residents upon request. Visit www.med-project.org/SF to order a mail-back package.

TAKE-BACK EVENTS



Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. Visit www.med-project.org/SF for information on events in your area.



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

Front of insert

UNWANTED OR EXPIRED MEDICATIONS



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

NOT ACCEPTED: Herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, aerosols, medical devices, sharps, illicit drugs and iodine-containing medications.

Front of insert

MAIL-BACK PACKAGE IS FOR

IODINE-CONTAINING MEDICATIONS



ACCEPTED: lodine-containing medications in any dosage form, in their original container or sealed bag.

NOT ACCEPTED: Unwanted medicines, herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, aerosols, medical devices, sharps and illicit drugs.

Front of insert

MAIL-BACK PACKAGE IS FOR INHALERS



ACCEPTED: Inhalers.

NOT ACCEPTED: Unwanted medicines, herbal remedies, vitamins, supplements, cosmetics, other personal care products, aerosols, medical devices, sharps, illicit drugs and iodine-containing medications.

MAIL-BACK PACKAGE IS FOR

PRE-LOADED
PRODUCTS
CONTAINING A
SHARP AND
AUTO-INJECTORS

ACCEPTED: Pre-loaded products containing a sharp and auto-injectors.

minni

NOT ACCEPTED: Unwanted medicines, herbal remedies, vitamins, supplements, cosmetics, other personal care products, inhalers, aerosols, medical devices, sharps, illicit drugs and iodinecontaining medications.

MED-Project

Medication Education & Disposal

DISPOSAL OPTIONS:

CHECK THE PACKAGE

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

Mail-back services for Unwanted Medicines, iodine-containing medications, pre-filled injector products, and inhalers are available in your area. Visit www.MED-Project.org to order a mail-back package.

2 CONVENIENT LOCATIONS

To find convenient locations in your area, visit www.MED-Project.org for more information. Mail-back distribution locations may also be available in your area.

TAKE-BACK EVENTS

Local take-back events offer residents a free and convenient way to dispose of expired or unwanted medicines. Visit www.MED-Project.org for information on events in your area.

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

Appendix P

Sample Digital and Local Social Networks

The following is a representative list of local organizations and their social media networks in the County. MED-Project will reach out to relevant groups to help promote the Program.

OUTLET	FACEBOOK	TWITTER
San Francisco Department of Public Health	https://www.facebook.com/San-Francisco-Health- Network	@SF_DPH
University of San Francisco Medical Center	https://www.facebook.com/UCSFMedicalCenter	@UCSFHospitals
Zuckerberg San Francisco General Hospital	https://www.facebook.com/Zuckerberg-San-Francisco-General	
Kaiser Permanente	https://www.facebook.com/kpthrive	@KPShare
Dignity Health	https://www.facebook.com/dignitymedicalgroupss	@dignitymedgroup
Chinese Hospital	https://www.facebook.com/chinesehospitalsf	
Sutter Health	https://www.facebook.com/SutterHealth	@SutterHealth
San Francisco VA Health System	https://www.facebook.com/VeteransAffairs	@DeptVetAffairs
UCSF Benioff Children's Hospital	https://www.facebook.com/UCSFBenioffChildrens	@UCSFChildrens
SF Department of the Environment		@SFEnvironment
San Francisco Unified School District	https://www.facebook.com/SFUnified/	@SFUnified
San Francisco Public Utilities Commission	https://www.facebook.com/SFWater/	
City and County of San Francisco	https://www.facebook.com/SF	@SFGOV

San Francisco Police Department	https://www.facebook.com/SFPD	@SFPD
San Francisco Medical Society	https://www.facebook.com/San-Francisco-Medical- Society	@SFMedSociety
California Pharmacist Association	https://www.facebook.com/CAPharm	@CAPharm
California Nurses Association	https://www.facebook.com/nationalnurses	@NationalNurses
National Association of Social Workers California	https://www.facebook.com/naswca	@naswca
San Francisco Fire Department	https://www.facebook.com/yoursffd	@sffdpio
University of California San Francisco	https://www.facebook.com/ucsf	@UCSF
San Francisco State University	https://www.facebook.com/sanfranciscostate	@SFSU
University of San Francisco	https://www.facebook.com/University.of.San.Francisco	@usfca
City College of San Francisco	https://www.facebook.com/City-College-of-San- Francisco	
The San Francisco LGBT Center	https://www.facebook.com/sflgbtcenter	@sflgbtcenter
Chinese American Community Foundation	https://www.facebook.com/Chinese-American-Community-Foundation-198288093627547/	@chinesegiving
Latino Community Foundation	https://www.facebook.com/latinocommunityfoundation	@LationCommFdn
San Francisco Chronicle	https://www.facebook.com/SFGate/	@SFGate
NBC Bay Area	https://www.facebook.com/NBCBayArea/	@nbcbayarea
KFOG Radio	https://www.facebook.com/kfogradio	@kfogradio

San Francisco Parent Teacher Association		@SanFranciscoPTA
California	https://www.facebook.com/WeAreCTA	@WeAreCTA
Teachers		
Association		