



SF Environment
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A Department of the City and County of San Francisco

Edwin M. Lee
Mayor

Deborah O. Raphael
Director

May 22, 2015

Regulatory Compliance Manager
[WHOLESALER NAME]
[ADDRESS]
[CITY], [STATE] [ZIP]

SUBJECT: Drug Wholesaler requirements under Safe Drug Disposal Stewardship Ordinance

Dear Compliance Manager:

We are writing to inform you of new requirements that may apply to your company under the San Francisco Safe Drug Disposal Stewardship Ordinance (Ordinance). The Ordinance was adopted by the San Francisco Board of Supervisors on March 17, 2015, and has an Effective Date of April 25, 2015. The Ordinance requires drug manufacturers to establish an industry-funded program to collect and properly dispose of unwanted medicines, generated in the home, from residents of the City and County of San Francisco (City).

We are contacting you because your company is licensed as a Pharmaceutical Drug Wholesaler by the California Board of Pharmacy. The Ordinance requires your company, as a "drug wholesaler," to provide the San Francisco Department of the Environment with a list of the manufacturers of covered drugs you resell or distribute for residential use in the City. This list must be submitted by June 25, 2015, and by January 15 annually thereafter. We will use the information you provide to notify manufacturers (called "producers" in the Ordinance) of covered drugs about the Ordinance and their responsibilities. Wholesalers have no other obligations under the Ordinance.

The entire Ordinance (San Francisco Environment Code, Sections 2200-2219) can be viewed online at www.sfenvironment.org/epr/meds. The following definitions from Section 2202 of the Ordinance are provided below for your convenience:

- **"Covered Drug"** means a drug sold in any form and used by City residents, including prescription, nonprescription, brand name and generic drugs.
 - o "Covered Drug" does not include:
 1. vitamins or supplements
 2. herbal-based remedies and homeopathic drugs, products, or remedies
 3. 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)
 4. drugs for which Producers provide a pharmaceutical product stewardship or take-back program as part of a federal Food and Drug Administration-managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1)

5. drugs that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date of this Ordinance if the Producer already provides a pharmaceutical product stewardship or take-back program
 6. medical devices or their component parts or accessories
- **"Drug Wholesaler"** means a Person who buys Drugs for resale and distribution to corporations, individuals, or entities other than consumers.
 - **"Person"** means a human being, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other entity of any kind or nature.
 - **"Producer"** means a Manufacturer engaged in the Manufacture of a Covered Drug sold in the City, including a brand-name or generic Drug.
 - o "Producer" does not include
 1. a retailer whose store label appears on a Covered Drug or the drug's packaging if the retailer identifies the manufacturer from whom the retailer obtains the drug
 2. a Repackager if the repackager identifies the manufacturer from whom the Repackager obtains the Drug
 3. a pharmacist who compounds or repackages a prescribed individual drug for a consumer
 4. or a wholesaler who is not also the Manufacturer

Requirements for Drug Wholesalers under the Ordinance

The Ordinance requires that each drug wholesaler that sells or distributes any covered drug in or into the City provide a list of the producers of those covered drugs to the San Francisco Department of the Environment. If the Ordinance does not apply to you because you do not currently sell or distribute covered drugs in or into the City, please complete a short online certification form on our website, www.sfenvironment.org/epr/meds.

If the Ordinance does apply to you, Section 2210 of the Ordinance requires that your list of producers be submitted in a form prescribed by the Director of the Department. Please go to www.sfenvironment.org/epr/meds for a template and instructions on how to submit your list of producers. Lists should be submitted in Microsoft Excel .xlsx or .xls format, within 60 days after the effective date of the Ordinance.

Your initial submittal is due June 25, 2015. Wholesalers are required to update and resubmit their list of producers by January 15 annually thereafter. Wholesalers have no other obligations under the Ordinance. For questions or additional information, please visit our website at www.sfenvironment.org/epr/meds or contact us by email at SafeMeds@sfgov.org.

Sincerely,



Deborah O. Raphael
Director