ORDINANCE NO. _____

ORDINANCE AMENDING THE ALAMEDA COUNTY ORDINANCE CODE BY ADDING CHAPTER 6.53, SECTIONS 6.53.010 THROUGH 6.53.130 TO: REQUIRE ANY PERSON WHO PRODUCES A DRUG OFFERED FOR SALE IN ALAMEDA COUNTY TO PARTICIPATE IN AN APPROVED DRUG STEWARDSHIP PROGRAM FOR THE COLLECTION AND DISPOSAL OF UNWANTED DRUGS FROM RESIDENTIAL SOURCES; PROVIDE FOR IMPLEMENTATION, ENFORCEMENT, FEES, AND PENALTIES; AND PHASE-IN THE APPLICATION OF THE CHAPTER TO NON-PRESCRIPTION DRUGS AND CONTROLLED SUBSTANCES; AND MAKING ENVIRONMENTAL FINDINGS.

WHEREAS, the County of Alameda has a substantial interest in having a drug stewardship program; and

WHEREAS, the County of Alameda has chosen to exercise its political power to have a drug stewardship program; and

NOW THEREFORE, the Board of Supervisors of the County of Alameda ordains as follows:

Title 6 of the Alameda County Health and Safety Code is hereby amended by adding Chapter 6.53, Sections 6.53.010 through 6.53.130, to read as follows:

6.52.010 - Declaration of findings.

The Board of Supervisors does hereby declare as follows:

A. Drugs are a necessary medical technology that successfully allows us to live longer, healthier, and more productive lives.

B. Pharmaceutical residues have been proven to be accumulating in ground water and drinking water. Drugs enter the environment through multiple sources primarily through excretion as waste, disposal directly in to the environment through flushing down toilets, or through leachate leaks in landfills. Municipal wastewater treatment plants were designed to treat biological agents in drinking water. Costs to develop waste treatment through wastewater treatment is extremely high, thus drugs pass through wastewater treatment systems and contaminate receiving waters.

C. Studies reveal stable concentrations of a variety of common drugs continue to mount including the 2001 US Geological Survey Report (1), the report for the San Francisco Estuary Institute (2) and investigative research by the Associated Press, all detected various common drugs in US and Bay Area water bodies.

(1) Kolpin, Dana et al. (2002) Pharmaceuticals, hormones and other organic wastewater contaminants in U.S. Streams, 1999-2000: A

National Reconnaissance, Environmental Science and Technology v. 36: 1202-1211.

(2) Oros, Daniel and David, Nicole (2002). Identification and Evaluation of Unidentified Organic Contaminants in the San Francisco Estuary, San Francisco Estuary Regional Monitoring Program for Trace Substances, SFEI

(3) Donn, J, Mendoza, M & Pritchard, J. AP Probe Finds Drugs in Drinking Water, 2008

D. A study released in January 2010 by the Maine Department of Environmental Protection detected the presence of over 40 drug compounds including antibiotics, steroids, antidepressants and pain medications in municipal solid waste landfill leachate (the liquid collected from the bottom of landfills). Landfill leachate is eventually treated by the same sewer treatment plants which are unable to treat the drugs found in wastewater.

E. According to the American Association of Poison Control Centers, 51% of all poisonings are attributed to pharmaceuticals. 41% of these are in children under 6 years old. 70% of visits to the emergency department are due to pharmaceutical poisonings. Poisoning is the fastest rising cause of accidental death among older adults, particularly from overdoses of over-the-counter, prescription and illicit drugs. (American Public Health Association, The Nation's Health, August ed., 2007) In Alameda County nonfatal hospitalized injuries from unintentional poisonings for adults 60 and older increased 43% from 1998 to 2006.

F. Prescriptions for controlled substances increased by 154% between 1993 and 2003. In the same period there has been a 90% increase in hospital visits due to prescription drug abuse and a 207% increase in hospital visits for teenage prescription drug abuse. 15 million American's currently abuse prescription drugs, which are the second only to marihuana. The Partnership for a Drug Free America released a report in February 2010 indicating that over 60% of teens are able to obtain prescription painkillers for free through friends or family.

G. Hydrocodone and oxycodone or "Oxys" are implicated in 28% of all drug related crime. And methylphenidate and dextromethorphan, "meth" are involved in 19% of all drug related crime.

H. Properly disposing of leftover, expired and unwanted drugs would be a significant step forward in preventing unintentional poisoning deaths attributable to drugs, abuse related to access to pharmaceuticals and concentrations of medicines reaching our drinking water.

I. Extended Producer Responsibility, also called Product Stewardship, is a strategy that places a shared responsibility for end-of-life management of consumer products on the manufacturers of the products, while encouraging product design that

minimizes negative impacts on human health and the environment at every stage of the product's lifecycle.

J. In 2009 and 2010, California passed three significant product stewardship bills for mercury thermostats, carpet, and paint. All three bills require producers to establish and fund product stewardship programs for their waste stream.

K. California Senate Bill 966, enacted as Chapter 542 of the Statutes of 2007, required CalRecycle to survey existing drug collection programs, evaluate them for several factors including cost effectiveness, and make recommendations for implementation of statewide programs. Recommendations have been returned to the state legislature for further action.

L. There is no permanent drug collection program in Alameda County, but there is considerable demand for it. In 2009, Bay Area residents disposed of over 60,000 lbs of unwanted pharmaceuticals in the 128 sites. Alameda county citizens returned just roughly 4000 lbs compared to Santa Clara County which disposed of almost 19,000 lbs and San Mateo which disposed of close to 18,000 pounds.

M. United States Senate Bill 3397, the "Secure and Responsible Drug Disposal Act of 2010," which was signed into law on October 12, 2010, authorizes the Attorney General to increase the methods—currently restricted to law enforcement—by which controlled substances may be collected, including collection at pharmacies. The goal of the bill is to increase opportunities for drug collection in order to reduce the instances of diversion and release of harmful substances into the environment.

N. A number of States introduced drug product stewardship bills recently including Maine, Maryland, Minnesota, Rhode Island, Florida, Oregon, and Washington.

O. A number of Canadian provinces and other countries have active, well-established drug product stewardship programs in place: British Columbia, Canada, has had a manufacturer-funded drug collection program in place since 1996; Ontario began program in July 2010, and Manitoba will begin its program in April 2011. France, Spain and Portugal, among others, have national, well-established, manufacturer-funded drug collection programs.

P. To date, there is no voluntary or mandatory statewide drug stewardship program for unwanted drugs in California, and drug companies have not offered any support for a collection program to date.

Section 6.53.020 - Title

This Chapter may be cited as the “Alameda County Safe Drug Disposal Ordinance.”

Section 6.53.030 - Definitions.

For the purposes of this Chapter, the following terms have the meanings given.

1. "Cosmetics" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles.

2. "Covered product" means all prescription drugs and all nonprescription drugs, including both brand name and generic drugs that do not also meet the definition of "cosmetics".

3. "Department" means the County's Department of Environmental Health.

4. "Drug wholesaler" means a business that sells or distributes drugs for resale to an entity other than a consumer.

5. "Drugs" means: (1) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias; (2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or (4) substances intended for use as a component of any substances specified in this subdivision, but not including medical devices or their component parts or accessories.

6. "Entity" means a person other than an individual.

7. "Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.

8. "Mail-back program" means a system whereby residential generators of unwanted products obtain prepaid and preaddressed mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

9. "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

10. "Person" means an individual, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

11. "Plan" means a product stewardship plan required under this Chapter that describes the manner in which a product stewardship program will be provided.

12. "Prescription drug" means any drug that by federal or state law may be dispensed lawfully only on prescription

13. "Producer" means a Person or Entity that: (1) has a physical presence in the United States and causes a covered drug to be manufactured or has legal ownership of the brand, brand name, or co-brand under which a covered drug is sold; or (2) imports a covered drug branded or manufactured by a person or entity that has no physical presence in the United States. "Producer" does not include: (1) a retailer that puts its store label on a covered drug unless the retailer imports the covered drug directly from a person that has no physical presence in the United States, or (2) a pharmacist who compounds a prescribed individual drug product for a patient.

14. "Product stewardship program" means a program financed and operated by producers to collect, transport, and recycle unwanted products.

15. "Residential generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned, such as hospice services, nursing homes, boarding care homes, schools, foster care, day care, and other locations where people, pets, or both reside on a temporary or permanent basis. "Residential generators" do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.

16. "Stewardship organization" means an organization designated by a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

17. "Unwanted product" means any covered product no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

Section 6.53.040. - Product stewardship program.

A. Requirement for sale. On and after January 1, 2012, all producers of covered products sold in the County of Alameda, including both incorporated and unincorporated territory within the County, shall participate in a product stewardship program to collect and dispose of unwanted products from residential generators. However, this Chapter shall not apply to the City of Berkeley. Each producer must:

1. Operate, individually or jointly with other producers, a product stewardship program approved by the Department; or

2. Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the Department.

B. Product stewardship program costs.

1. A producer, group of producers, or stewardship organization must pay all administrative and operational costs associated with their product stewardship program, including the cost of collecting, transporting, and

disposing of unwanted products collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted product.

2. No person may charge a fee to cover the costs of a product stewardship program at the time of sale of the covered product or when unwanted products are collected from residential generators or delivered for disposal.

6.53.050 - Product stewardship plan.

A. Plan content. A product stewardship plan must contain the following:

1. Certification that the product stewardship program will accept all unwanted products regardless of who produced them, unless excused from this requirement by the Department as part of the approval of the plan;

2. Contact information for the individual and the entity submitting the plan and for all producers participating in the product stewardship program;

3. A description of the methods by which unwanted products from residential generators will be collected in the County, including the location of each collection site and locations where envelopes for a mail-back program are available, and an explanation of how the collection system will be convenient and adequate to serve the needs of County residents;

4. A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each transporter and each medical waste disposal facility proposed to participate in the product stewardship program;

5. A description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;

6. A description of the public education effort and outreach activities required under this Chapter and how their effectiveness will be evaluated;

7. A description of how the scope and extent of the stewardship program are consistent with the scope and extent of the sales of covered products within the County by the producer or group of producers; and,

8. A starting date when collection of unwanted products will begin.

B. Department review and approval; updates.

1. No producer, group of producers, or stewardship organization may begin collecting unwanted products until it has received written approval of its product stewardship plan from the Department.

2. Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by June 1, 2012.

3. Within 90 days after receipt of a plan, the Department shall conduct a noticed public hearing and determine whether the plan complies with the requirements of this Chapter and of any regulations adopted pursuant to this Chapter. As part of its approval, the Department may set reasonable performance goals for the program. If the Department approves a plan, it shall notify the applicant of its approval in writing. If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. An applicant whose plan has been rejected by the Department must submit a revised plan to the Department within 60 days after receiving notice of the rejection.

4. At least every three years, a producer, group of producers or stewardship organization operating a product stewardship program must update its product stewardship plan and submit the updated plan to the Department for review and approval.

5. A producer who begins to offer covered products for sale in Alameda County after January 1, 2012, must submit a product stewardship plan to the Department or provide evidence of having joined an existing approved plan at least 90 days prior to the producer's initial offer of sale of covered products.

6. Any proposed changes to a product stewardship plan must be approved by the Department in writing.

6.53.060 - Disposal of unwanted products.

A. Compliance with applicable law. Each product stewardship program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of medical waste and controlled substances.

B. Disposal at medical waste facility. Each product stewardship program must dispose of all unwanted products from residential generators at a medical waste facility. The medical waste facility must be in possession of all required regulatory permits and licenses.

C. Product stewardship programs may petition the Department for approval to use final disposal technologies, where lawful, that provide superior environmental and human health protection than provided by current medical waste disposal technologies

for covered products if and when those technologies are proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of the following areas:

1. Monitoring of any emissions or waste;

2. Worker health and safety;

3. Air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and,

4. Overall impact on the environment and human health.

D. Packaging separation. Each product stewardship program is encouraged to separate unwanted products from their original containers, when appropriate, prior to collection or disposal.

6.53.070 - Product stewardship program promotion and outreach.

A. A product stewardship program must promote the program to residential generators, pharmacists, retailers of covered products, and health care practitioners as the proper and safe method to dispose of unwanted drugs.

B. A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations in the County and disseminate the materials to health care facilities, pharmacies, and other interested parties. The program must also establish a website publicizing collection locations and program operations and a toll-free telephone number that residential generators can call to find nearby collection locations and understand how the program works.

6.53.080 - Report.

A. On or before May 1, 2013, and in each subsequent year, every producer, group of producers, or stewardship organization operating a product stewardship program must prepare and submit to the Department an annual report describing the program's activities during the previous reporting period. The report must include the following:

1. A list of producers participating in the product stewardship program;

2. The amount, by weight, of unwanted products collected from residential generators collected at each drop-off site and in the entire County and the total amount by weight collected by a mail-back program, if applicable;

3. A description of the collection system, including the location of each collection site and locations where envelopes for a mail-back program are provided, if applicable;

4. The name and location of disposal facilities at which unwanted products were disposed of and the weight of unwanted products collected from residential generators disposed of at each facility;

5. Whether policies and procedures for collecting, transporting, and disposing of unwanted products, as established in the plan, were followed during the reporting period and a description of any noncompliance;

6. Whether any safety or security problems occurred during collection, transportation, or disposal of unwanted products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;

7. A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and program activities;

8. How the product stewardship program complied with any other elements in the plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the program; and

9. Any other information that the Department may reasonably require.

B. For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

6.53.090. - Drug wholesaler responsibilities.

A. The Department shall provide on its website a list of all producers participating in product stewardship programs approved by the Department and a list of all producers the Department has identified as noncompliant with this Chapter or any regulations adopted pursuant to this Chapter.

B. Beginning 10 days after the effective date of the legislation adopting this Chapter, any drug wholesaler offering covered products for sale in the County must provide a list of the producer or producers of those products to the Department. Wholesalers must submit an updated list to the Department by January 15 of each year, beginning January 15, 2013.

6.53.100. - Regulations and fees.

A. The Director of the Department of Environmental Health may, after a noticed public hearing, adopt such rules and regulations as necessary to implement, administer, and enforce this ordinance.

B. No later than February 1, 2012, the Department shall submit to the Board of Supervisors a proposed schedule of fees to be charged producers to cover the County's costs of administering and enforcing this ordinance, including education and outreach programs.

6.53.110. - Enforcement.

A. The Department of Environmental Health shall administer the penalty provisions of this Chapter.

B. The Department of Environmental Health may issue an administrative citation to a producer for violation of this Chapter or any regulation adopted pursuant to this Chapter. The Department shall first send a written warning to the producer as well as a copy of this Chapter and any regulation adopted pursuant to this Chapter. The producer shall have 30 days after receipt of the warning to come into compliance and correct any violations.

C. If the producer fails to come into compliance or correct any violations, the Department of Environmental Health may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.

D. Any person in violation of this Chapter or any regulation adopted pursuant to this Chapter shall be liable to the County of Alameda for a civil penalty in an amount not to exceed one thousand dollars ($1,000) per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

E. In determining the appropriate penalties, the Department of Environmental Health shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

F. Any producer receiving an administrative citation under this Chapter or any regulation adopted pursuant to this Chapter may appeal it within 21 calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or County holiday, then the deadline shall be extended until the next regular business day.

The request to appeal must:

1. Be in writing;

2. Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;

3. Specify the basis for the appeal in detail;

4. Be postmarked within 21 days from the date the administrative citation was issued; and

5. Be sent to the address as set forth on the administrative citation.

G. The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a hearing officer appointed by the Director of the Department of Environmental Health. Written notice of the time and place for the hearing will be served by first class mail or personal service at least 21 days prior to the date of the hearing to the producer appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.

H. The failure of any producer to receive notice of the hearing shall not affect the validity of any proceedings under this Chapter. Failure of any producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that producer's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees.

I. A hearing officer shall be designated by the Director of the Department of Environmental Health for hearings under this Chapter. The producer requesting the appeal may request the Director of the Department of Environmental Health to recuse a hearing officer for reasons of actual prejudice against the party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence as follows:

1. A valid administrative citation shall be prima facie evidence of the violation;

2. All testimony shall be by declaration under penalty of perjury;

3. The producer responsible for the violation or any other interested person may present testimony or evidence concerning the violation.

4. The hearing officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The hearing officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.

5. The hearing officer shall make findings based on the record of the hearing and make a written decision based on the findings. The decision shall be served by first class mail on all parties. The decision of the hearing officer affirming or dismissing the administrative citation is final.

J. The Department of Environmental Health may establish appropriate administrative rules for implementing this Chapter, conducting hearings, and rendering decisions pursuant to this section.

K. Upon the failure of any producer to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the County Counsel's Office may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such person from continuing any prohibited activity and compelling compliance with lawful requirements.

L. Any person who knowingly and willfully violates the requirements of this Chapter or any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and upon conviction thereof is punishable by a fine of not less than fifty dollars ($50) and not more than five hundred ($500) for each day per violation, or by imprisonment in the County Jail for a period not to exceed six (6) months, or by both such fine and imprisonment.

M. Any producer alleged to be in violation of this Chapter may raise a lack of sufficient contacts with the jurisdiction as a defense under the United States Constitution to any enforcement action.

6.53.120. - Implementation.

A. Notwithstanding any other provision of this Chapter, "covered product," shall not include any "nonprescription drug," until January 1, 2013.

B. The Department of Environmental Health shall submit recommendations to the Board of Supervisors no later than September 1, 2012, regarding whether to continue to include nonprescription drugs under this Chapter and, if so, how best to do so.

C. Notwithstanding any other provision of this Chapter, "covered product," as defined in this Chapter, shall not include any controlled substance until January 1, 2013, or until 90 days after the effective date of regulations adopted by the Attorney General of the United States for the delivery of controlled substances by ultimate users for disposal under Title 21 of the United States Code, Section 822(g) ("Secure and Responsible Drug Disposal Act of 2010"), whichever comes later. "Controlled substance" for purposes of this Section shall mean any substance listed under California Health and Safety Code Sections 11053 through 11058 or Title 21 of the United States Code, Sections 812 and 813 or any successor legislation.

D. The Department of the Environmental Health shall submit recommendations to the Board of Supervisors no later than September 1, 2012, regarding whether to continue to include controlled substances under this Chapter and, if so, how best to address the legal requirements for disposal of such substances.

6.53.130 - Additional provisions.

A. Disclaimer. In adopting and implementing this Chapter, the County of Alameda is assuming an undertaking only to promote the general welfare. It is not

assuming, nor is it imposing on its officers and employees, an obligation for breach of which it is liable in money damages to any person who claims that such breach proximately caused injury.

B. Conflict with State or Federal Law. This Chapter shall be construed so as not to conflict with applicable federal or state laws, rules or regulations. Nothing in this Chapter shall authorize any County agency or department to impose any duties or obligations in conflict with limitations on municipal authority established by state or federal law at the time such agency or department action is taken. The County shall suspend enforcement of this ordinance to the extent that said enforcement would conflict with any preemptive state or federal legislation subsequently adopted.

C. Severability. If any of the provisions of this Chapter or the application thereof to any person or circumstance is held invalid, the remainder of those provisions, including the application of such part or provisions to persons or circumstances other than those to which it is held invalid shall not be affected thereby and shall continue in full force and effect. To this end, the provisions of this Chapter are severable.

D. Environmental Findings. The County has determined that the actions contemplated in this ordinance are in compliance with the California Environmental Quality Act (Cal. Pub. Res. Code §§ 21000 et seq.). Said determination is on file with the Clerk of the Board of Supervisors in File No. _____ and is incorporated herein by reference.

Adopted by the Board of Supervisors of the County of Alameda, State of California, on _____, 2011, by the following called vote:

AYES:

NOES:

EXCUSED:

_____
NATE MILEY, President
Board of Supervisors
County of Alameda, State of California

ATTESTED TO:

CRYSTAL K. HISHIDA-GRAFF, Clerk
Board of Supervisors, County of Alameda

By:_____

APPROVED AS TO FORM:

RICHARD R. KARLSSON
Interim County Counsel

By:_____