File No. 100455 Committee Item No. _____
Board Item No. 10

COMMITTEE/BOARD OF SUPERVISORS

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Completed by: R. Craig Date 12-2-10
Completed by: _____ Date _____

An asterisked item represents the cover sheet to a document that exceeds 20 pages. The complete document is in the file.

[San Francisco Safe Drug Disposal Ordinance.]

Ordinance amending the San Francisco Environment Code by adding Chapter 22, Sections 2201 through 2211 ~~2211~~, to; require any person who produces a drug offered for sale in San Francisco to participate in an approved drug stewardship program for the collection and disposal of unwanted drugs from residential sources; ~~, and to~~ 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.

NOTE: Additions are *single-underline italics Times New Roman*; deletions are ~~*strike-through italics Times New Roman*~~. Board amendment additions are double-underlined; Board amendment deletions are ~~strikethrough normal~~.

Be it ordained by the People of the City and County of San Francisco:

Section 1. **Findings.**

(a) Drugs allow us to live longer, healthier, and more productive lives.

(b) Municipal wastewater treatment plants are not designed to treat complex drugs compounds that end up in the sewer system from being flushed down toilets and sinks. As a result, drugs can pass through wastewater treatment systems and contaminate receiving waters.

(c) Recent water studies by the US Geological Survey and the San Francisco Estuary Institute detected various common drugs in US and Bay Area water bodies.

(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) Properly disposing of leftover, expired and unwanted drugs would be a step forward in preventing unintentional poisoning deaths attributable to drugs. A 2004 report by the Centers for Disease Control states that nearly all unintentional poisoning deaths in the US are attributed to drugs, most of which come from the abuse of prescription and illegal drugs. In 2004, 20,950 people died of drug poisoning. 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.

(f) 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.

(g) San Francisco passed a Producer Responsibility Resolution in 2006 and in 2010 to state its support for managing product waste under an Extended Producer Responsibility (EPR) system. Many other local and national government bodies support EPR including CalRecycle (formerly the California Integrated Waste Management Board), the National Association of Counties and the National League of Cities.

(h) 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.

(i) 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.

(j) ~~(h)~~ There is no permanent drug collection program in San Francisco, but there is considerable demand for it. San Francisco's Department of the Environment ("SFE") and Public Utilities Commission ("PUC") annually receive thousands of calls from concerned residents requesting information about proper drug disposal. In May 2006, SFE and PUC ~~San Francisco's Department of the Environment (SFE) and Public Utilities Commission (PUC)~~, in partnership with Walgreens, organized a large-scale drug collection pilot event at 13 Walgreens locations over a 2-day period. More than 500 residents participated, bringing in 1130 pounds of drugs. Due to lack of funding and pharmacy partnerships, this program could not be implemented permanently. Since 2009, SFE and PUC have been piloting a drug mail-in program. San Francisco residents requested more than 9,000 mail-back envelopes within the first 18 months of the program. At a cost of $3.75 per envelope, this program is unsustainable without additional funding sources. ~~annually receive thousands of calls from concerned residents requesting information about proper drug disposal.~~

(k) 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.

(l) ~~(i)~~ A number of States introduced drug product stewardship bills in the 2009-2010 ~~this~~ legislative year including Maine, Maryland, Minnesota, Rhode Island, Florida, Oregon, and Washington.

(m) ~~(j)~~ A number of Canadian provinces and other countries have active, well-established drugs product stewardship programs in place; ~~.~~ British Columbia~~, Canada,~~ has had a manufacturer-funded drug collection program in place since 1996; Ontario began a

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.

(n) ~~(k) To date, there~~ 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 2. The San Francisco Environment Code is hereby amended by adding Chapter 22, Sections 2201 through 2211, to read as follows:

SEC. 2201. TITLE.

This Chapter may be cited as the San Francisco Safe Drug Disposal Ordinance.

SEC. 2202. 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. ~~1.~~ *"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. ~~2.~~ *"Department" means the Department of the Environment.*

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

5. ~~4.~~ *"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. ~~5.~~ *"Entity" means a person other than an individual.*

7. ~~6.~~ *"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. ~~7.~~ *"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. ~~8.~~ *"Nonprescription drug" means any drug that may be lawfully sold without a prescription.*

10. ~~9.~~ *"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. ~~10.~~ *"Plan" means a product stewardship plan required under Section 2204 that describes the manner in which a product stewardship program will be provided.*

12. ~~11.~~ *"Prescription drug"* means any drug that by federal or state law may be dispensed lawfully only on prescription ~~has the meaning given in section [2.21151.44, paragraph (d)]~~.

13. ~~12.~~ *"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. ~~a person who has legal ownership of the brand, brand name, or co-brand of a covered product or manufactures a generic covered product sold in San Francisco. "Producer" does not include a retailer who: (a) puts its store label on a covered product; (b) imports a covered product branded or manufactured by a producer who meets the requirements of this subsection and who has no physical presence in the United States; or (c) sells at wholesale a covered product, does not have legal ownership of the brand, and elects to fulfill the responsibilities of the producer for that product.~~

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

15. ~~14.~~ *"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. ~~15.~~ *"Stewardship organization" means an organization designated by a* producer or *group of producers to act as an agent on behalf of each producer to operate a product stewardship program.*

17. ~~16.~~ *"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.*

SEC. 2203. PRODUCT STEWARDSHIP PROGRAM.

*(a) **Requirement for** **participation** ~~**sale.**~~ On and after* September ~~August~~ *1, 2011,* all producers of ~~no producer or drug wholesaler may sell or offer for sale covered products in the City and County of San Francisco unless the producer of the~~ *covered products* sold in the City and County of San Francisco shall participate ~~participates~~ *in a product stewardship program to collect and dispose of unwanted products from residential generators. 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, as well as the cost of public outreach and education, and program evaluation.

(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.

SEC. 2204. 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 City, including the location of each collection site and/or 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 City 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 ~~hazardous~~ *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 Section 2206 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 City by the producer or group of producers; ~~and,~~

(8) A description of goals set for performance categories established by the Department; and,

(9) ~~(8)~~ *A starting date when collection of unwanted products will begin.*

*(b) **Department** **template development**, **review and approval; updates.***

(1) By February 1, 2011, the Department shall develop a stewardship plan template to be used by producers, groups of producers, or stewardship organizations. The template shall include performance categories that producers, groups of producers, or

stewardhip organizations shall use to measure the success of their product stewardship plans and set measurable goals for the development of the plans.

(2) ~~(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.*

(3) ~~(2)~~ *Product stewardship plans must be submitted to the Department for approval. The initial plans must be submitted by* April ~~February~~ *1, 2011.*

(4) ~~(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. 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* 30 ~~60~~ *days after receiving notice of the rejection.*

(5) ~~(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.*

(6) ~~(5)~~ *A producer who begins to offer covered products for sale in San Francisco after August 1, 2011, 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.~~

(7) ~~(6)~~ *Any proposed changes to a product stewardship plan must be approved by the Department in writing.*

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SEC. 2205. 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** ~~**hazardous**~~ ***waste facility.*** *Each product stewardship program must dispose of all unwanted products from residential generators at a* medical ~~hazardous~~ *waste facility.* ~~Unwanted products from residential generators otherwise retain all other generator exemptions for household hazardous waste.~~ *The* medical ~~hazardous~~ *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 toxi 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.*

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SEC. 2206. 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 City and disseminate the materials to health care facilities, pharmacies, and other interested parties. The program must also establish a web site publicizing collection locations and/*or envelope distribution points*, program operations and a toll-free telephone number that residential generators can call to find nearby collection locations and understand how the program works.*

SEC. 2207. REPORT.

(a) On or before December ~~November~~ *1, 2012, 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 City 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, and an evaluation of how convenient and adequate the system is in serving the needs of City residents;

(4) The name of transporters used, *and* 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) If packaging was separated from the unwanted product prior to disposal of the unwanted product, the amount and percentage of packaging recycled and the name and location of the material recovery facility to which it was delivered;~~

(5) ~~(6)~~ *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) ~~(7)~~ *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) ~~(8)~~ *A description of public education and outreach activities implemented during the reporting period,* an evaluation of their effectiveness, and ~~including~~ *the methodology used to evaluate the outreach and program activities;*

(8) ~~(9)~~ *How the product stewardship program complied with any other elements in the plan approved by the Department,* including its degree of success in meeting the goals set for the performance categories established by the Department*; and*

(9) ~~(10)~~ *Any other information that the Department may reasonably require.*

(b) For the purposes of this section, "reporting period" means the period beginning September ~~August~~ *1 and ending* August ~~July~~ *31 of the* next ~~same~~ *calendar year.*

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SEC. 2208. DRUG WHOLESALER RESPONSIBILITIES.

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

~~(b) A drug wholesaler offering covered products for sale in the City is responsible for viewing the Department's web site to determine if a producer of products the wholesaler is offering for sale in the City is in compliance with this Chapter or any regulations adopted pursuant to this Chapter. If a drug wholesaler is unsure of the status of a producer or believes a producer is not in compliance, the drug wholesaler shall contact the Department to determine the producer's status.~~

(b) ~~(c)~~ *Beginning* 10 days after the effective date of the legislation adopting this Chapter ~~*November 1, 2010*~~, *any drug wholesaler offering covered products for sale in the City 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, 2012.

SEC. 2009. REGULATIONS; FEES.

(a) The Director of the Department of the Environment 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, 2011, the Department shall submit to the Board of Supervisors a proposed schedule of fees to be charged producers to cover the City's costs of administering and enforcing this Ordinance, including education and outreach programs.

(c) No later than January 1, 2014, the Department shall be regulation establish performance standards and recovery rates for drug stewardship programs covered by this Chapter.

SEC. 2210. ENFORCEMENT.

(a) The City Administrator shall, in ~~with the~~ *cooperation with the Department of the Environment, administer the penalty provisions of this Chapter.* ~~The Department shall work order, or other provide, sufficient funds to the City Administrator to pay for the costs incurred by the City Administrator in administering the penalty provisions.~~

(b) Upon receiving a complaint from the Department of a violation of this Chapter or any regulation adopted pursuant to this Chapter, the City Administrator shall send a written warning, as well as a copy of this Chapter and any regulations adopted pursuant to this Chapter, to the producer identified by the Department. 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 City Administrator or his or her designee may impose administrative fines for violations of this Chapter or of any regulation adopted pursuant to this Chapter. San Francisco Administrative Code Chapter 100, "Procedures Governing the Imposition of Administrative Fines," as amended, is hereby incorporated in its entirety and shall govern the imposition, enforcement, collection, and review of administrative citations issued to enforce this Chapter and any rule or regulation adopted pursuant to this Chapter. Each day shall constitute a separate violation for these purposes.

(d) Upon the failure of any person to comply with any requirement of this Chapter and any rule or regulation adopted pursuant to this Chapter, the City Attorney 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.

(e) 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.

(f) Any person in violation of this Chapter or any rule or regulation adopted pursuant to this Chapter shall be liable to the City and County of San Francisco 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. Civil penalties shall not be assessed pursuant to subsection (f) for same violations for which the Department assessed an administrative penalty pursuant to subsection (c).

(e) In determining the appropriate penalties, the court or the City Administrator 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 or other person 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.

SEC. 2211. IMPLEMENTATION.

(a) Notwithstanding any other provision of this Chapter, "covered product," as defined in Section 2202(1), shall not include any "nonprescription drug," as defined in Section 2202(7), until January 1, 2012.

(b) The Department of the Environment, in consultation with the Department of Public Health and the Public Utilities Commission, shall submit recommendations to the Board of Supervisors no later than December 1, 2011, 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 Section 2202(1), shall not include any controlled substance until January 1, 2012, 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 Environment, in consultation with the Department of Public Health and the Public Utilities Commission, shall submit recommendations to the Board of Supervisors no later than December 1, 2011, 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.

Section 3. **Additional Provisions.**

(a) **Disclaimer.** In adopting and implementing this Chapter, the City and County of San Francisco 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 City 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 City 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 Planning Department 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.

APPROVED AS TO FORM:
DENNIS J. HERRERA, City Attorney

By: _____
THOMAS J. OWEN
Deputy City Attorney