

**SUBMITTAL TO THE BOARD OF SUPERVISORS
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA**

107



FROM: Department of Environmental Health

SUBMITTAL DATE:
March 4, 2013

SUBJECT: Submission of a Grant Application to the California CUPA Forum Board

RECOMMENDED MOTION:

1. Authorize the Director of Environmental Health or designee to sign and submit the grant application (Attachment A) for \$30,340 to fund a study to determine if certain empty pharmaceutical waste containers meet hazardous waste criteria.
2. Authorize the Director of Environmental Health or designee to sign any grant related documents, if funded.

BACKGROUND:

The Department of Environmental Health Hazardous Materials Management Branch, was designated by the State of California, Environmental Protection Agency as the Certified Unified Program Agency (CUPA) or lead agency for the County in 1997. The State's goal in creating the

(continued)

SVS:JSW

Steve Van Stockum

Steve Van Stockum, Director

FINANCIAL DATA	Current F.Y. Total Cost:	N/A	In Current Year Budget:	N/A
	Current F.Y. Net County Cost:	N/A	Budget Adjustment:	N/A
	Annual Net County Cost:	N/A	For Fiscal Year:	13/14

SOURCE OF FUNDS: California CUPA Forum Board, Environmental Protection Trust Fund	Positions To Be Deleted Per A-30	<input type="checkbox"/>
	Requires 4/5 Vote	<input type="checkbox"/>

C.E.O. RECOMMENDATION:

APPROVE
Steven C. Horn
BY: _____
Steven C. Horn, MPA

County Executive Office Signature

FORM APPROVED COUNTY COUNSEL
BY: *Eric Stopher*
DATE: 3/5/13
Departmental Concurrence

- Policy
- Consent
- Policy
- Consent

Dep't Recomm.:
Per Exec. Ofc.:

Prev. Agn. Ref.: _____ **District:** All **Agenda Number:** _____

ATTACHMENTS FILED
WITH THE CLERK OF THE BOARD

2-9

BACKGROUND:

CUPA was to make hazardous materials and hazardous waste management programs within cities and counties more coordinated, consolidated, and consistent. The County, as the CUPA, is responsible for coordinating and implementing hazardous material/waste management programs countywide in order to accomplish this goal. The California CUPA Forum, a 501 (c) (3) organization, was formed to provide a single statewide organization consolidating Unified Program implementation efforts and representing all unified program agencies with a single voice. Cal-CUPA Forum strives to achieve consistency, consolidation, and coordination in the implementation of the Unified Program in an efficient and effective manner. The Environmental Protection Trust Fund was established by the Forum to manage and disburse grant monies from enforcement case settlements to enhance the investigation, inspection and enforcement of Unified Programs throughout the State of California.

This grant proposal seeks to fund a study at the University of California, Riverside under the oversight of the CUPA that would quantify how much residue, and subsequently waste material, is left in regulated empty containers. By quantifying this waste amount, a waste determination consistent with Title 22 California Code of Regulations §66262.11 will be performed that will either A) confirm the containers meet listed hazardous waste criteria; or B) reveal that the containers do not contain enough waste residue to consider them listed hazardous waste and thus provide scientific support to reduce the regulatory burden on businesses that generate this waste stream. The results of this study will be shared statewide with other CUPAs and State regulatory agencies.

FISCAL

The approval of this item will result in no cost to the County.

RE: Submission of a Grant Application to the California CUPA Forum Board
Date: March 4, 2013
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ATTACHMENT A

Riverside County CUPA Forum Board Grant Application February 2013



PO Box 2017
Cameron Park, CA 95682-2017

Trustees

- Michael Vizzier, *Chair*
- Elise Rothschild, *Secretary/Treasurer*
- Vince Mendes, *Trustee*
- Bill Jones, *Trustee*
- Eric Scott, *Trustee*

CUPA Forum Enforcement Issue Coordinator

Bill Jones, Los Angeles County Fire

Northern California

Eric Scott, Glenn County

Bay Area

Elise Rothschild, Sacramento County

Central California

Vince Mendes, Fresno County

Southern California

Michael Vizzier, San Diego County

CUPA Forum Board

Environmental Protection

Trust Fund Grant Application

(1) ENTITY INFORMATION

You must submit one (1) application per project. All applications will be scored as one complete application and not divided up. Your application will be accepted or denied as a whole. Grant applications must be from agencies implementing one or more of the Unified Programs (UP) or from entities other than a UP, if a majority of the Trustees agree that the proposal benefits UP implementation and enforcement. The department director or designee must sign this grant application.

Name of UPA or Other Entity:

Riverside County Department of Environmental Health

Name of Department Head, Director or Designee:

Steve Van Stockum

Name of Project Director:

Diane Christensen

Address:

4065 County Circle Drive, Room 104

City, State, Zip Code:

Riverside, CA 92513

Phone:

(951) 358-5055

Fax:

(951) 358-5017

E-Mail Address:

dchristensen@rivcocha.org

(1) ENTITY INFORMATION (CONTINUED)

Name of Grant Contact: (Contact for grant implementation, progress, etc)

Nicholas Crain

Address:

47950 Arabia St, Suite A

City, State, Zip Code:

Indio, CA 92201

Phone:

(760) 863-8976

Fax:

(760) 863-8303

E-Mail Address:

ncrain@rivcocha.org

Number of UP Staff: 29

Number of Regulated Facilities: ~7,000

Participate in the CUPA Forum: YES NO
(i.e. regional or TAG)

(2) EXECUTIVE SUMMARY

Provide a brief description of the purpose and benefits of the grant proposal.

The purpose of the proposal is to conduct a study of P-listed hazardous waste pharmaceuticals to test if the empty containers (specifically of P-listed warfarin and nicotine) meet the listing criteria for hazardous waste.

Currently, this waste stream is fully regulated as hazardous waste. The waste stream includes hazardous waste pharmaceuticals warfarin (e.g. Coumadin, Jantoven, etc.) and nicotine in the form of lozenges, gum, and patches (e.g. Nicorette, etc.), among other listed wastes. Most other P-listed waste streams have been excluded by Federal EPA for certain reasons, but not the aforementioned wastes. The management problem for regulated facilities generating this waste stream is that the waste stream not only includes the pills or product, but also includes the empty containers that formerly held the product due to the

(2) EXECUTIVE SUMMARY (CONTINUED)

regulation for P-listed wastes found in 40 CFR §261.33.

This proposal would be to fund a study at the University of California, Riverside under the oversight of the applicant that would quantify how much residue, and subsequently waste material, is left in regulated empty containers. By quantifying this waste amount, a waste determination consistent with 22 CCR §66262.11 will be performed that will either: A) Confirm the containers meet P-listed hazardous waste criteria; or B) Reveal that the containers do not contain enough waste residue to consider them P-listed hazardous waste. If A is confirmed, no change to industry occurs. If B is confirmed, there would be scientific support to reconsider regulation of a low to no risk waste stream for regulated facilities in the State of California, if not the nation.

The results would be made public to the extent feasible by the Department, including but not limited to the CUPA Forum Board.

(3) GRANT AMOUNT

Grant Amount Requested: \$

See attached Budget Justifications

(4) WORK PLAN: (SCOPE OF WORK)

The grant applicant shall develop a work plan as part of this grant application that describes the objective of the project, sustainability, anticipated goals, benefits to the UP and performance measures or measures of success in 1500 words or less. The scope of work could be as simple as describing equipment, purchase date, proposed use and benefit or as complex as a description of implementation activities, tasks and equipment to be purchased (or both). The work plan shall include a detailed timeline that delineates critical and completion dates of the activities and tasks. The work plan shall include a brief narrative summary for each activity and task that clearly describes the activity or task and depicts the steps that will be taken or the methods to be used for completion. The description(s) should include as much detail as necessary to depict the overall implementation efforts through the period of the grant. If applicable, the description should also include the degree of applicability to all elements of the UPs, e.g. hazardous waste, underground storage tanks, etc. and the degree that the proposal could be used by other agencies or replicated.

◀ Please Attach Work Plan to Application ▶

See Attached Work Plan

(5) PROJECTED BUDGET

Describe in line item detail, the expenditures, the appropriate Sales Tax and costs necessary to complete the project described in the Work Plan. The grant award must be used to pay for costs listed in this budget. The Trustees will consider "like for like" substitutions for approved grants, but the use of the grant award to pay for other costs not specified in the budget will likely be denied. The applicant will be required to provide evidence to verify that the grant allocation was used as specified in this budget.

◀ Please Attach Projected Budget to Application ▶

See attached Budget Justifications

(6) REIMBURSEMENT OPTIONS

If more than one option is selected, then the option(s) must be specified in line item detail in the project budget.

Receive approved grant monies up front (in July of the year grant is approved)

Submit invoice for reimbursement

Have CFB Trust pay supplying entity directly (subject to discretion of Trustees)

(7) GRANTEE APPLICANT SPECIFIC CERTIFICATIONS

These criteria are mandatory. Please check all that apply:

This grant will be used to supplement the annual budget of the Grantee. It will not be used to reduce or supplant the annual operating budget of the Grantee.

The grant applicant maintains an accounting system that is sufficient to track the use of Trust Fund monies and to report on these transactions as required under the terms of the grant.

Grant applicants requesting equipment purchases must certify that their organization maintains a fixed asset tracking system and a periodic inventory of equipment is performed. A copy of the first inventory following the purchase of equipment with Trust Funds must be submitted to the Trustees.

A copy of the invoice and a picture of equipment purchased with these funds must be submitted to the Trustees within one month of purchase.

Successful applicants must acknowledge the Trust Fund's right to conduct an audit of purchase(s) made with Trust Fund monies.

Grant funds must be expended for the purposes approved in the grant within two years or repaid to the Trust Fund, unless otherwise stipulated in the grant award.

(8) CERTIFICATION

I certify under penalty of perjury that the information I have entered on this application is true and complete to the best of my knowledge and that I am an employee of the applicant authorized to submit the application. All procedures and mandates have been followed in the preparation of this application, including financial procurement and when approvals are necessary from the governing body. I further understand that any false, incomplete, or incorrect statements may result in the disqualification of this application. By signing this application, I waive any and all rights to privacy and confidentiality of the proposal on behalf of the applicant.

Director/Department Head or Authorized Designee Signature:

Printed name of Director/Department Head or Authorized Designee:

Date:

Hazardous Waste P-Listed Pharmaceutical Container Study Scope of Work

Objective

Determine P-listing applicability of empty pharmaceutical containers by determining amount of residue in empty containers that held certain pharmaceuticals that when empty potentially become P-listed hazardous waste.

Benefits to the Unified Program

Results of the study will provide clarity to Unified Program participants (both regulators and industry) in the management of this unique waste stream. If the sample empty containers are determined to not meet the listing criteria, it would support claims of non-hazardous waste determination by generators of P-listed empty container waste, lifting a burden from the Unified Program participants, saving time during inspections as well as time devoted to education about this waste stream, and also reduce management and disposal costs to industry.

Sample Collection

- Samples will be collected from various retail pharmaceutical stores in Riverside County or at one central point of contact for one of multiple participating companies, and from one regulated facility in San Bernardino County utilizing proper chain of custody protocol. Samples obtained in San Bernardino County will be obtained by San Bernardino County Fire Department, Hazardous Materials Division personnel and delivered to a representative of Riverside County Department of Environmental Health. Due to the unknown quantity of containers able to be obtained, the total amount of containers included in the study is unknown. However, an approximate number of 45-80 container samples will be collected for analysis. They potentially will include the following in varying degrees of total quantity based on need or availability:
 - 1) Jantoven brand warfarin (1, 2, 2.5, 3, 4, 5, 6, 7.5, & 10 mg dose tablets) ~9 empty containers
 - 2) Coumadin brand warfarin (1, 2, 2.5, 3, 4, 5, 6, 7.5, & 10 mg dose tablets) ~9 empty containers
 - 3) Barr (or Teva) brand generic warfarin (1, 2, 2.5, 3, 4, 5, 6, 7.5, & 10 mg dose tablets) ~9 empty containers
 - 3) Any other marketed brand or generic supplier of warfarin, possibly an additional 9-27 empty containers
 - 4) Nicotine blister pack (gum, 2 & 4 mg; lozenge, 2 & 4 mg; patches, 7, 14, & 21 mg) ~7 empty containers
 - 5) Nicotine liquid stock bottle (high, medium, and low dose ranges) ~3 empty containers
 - 6) Physostigmine salicylate (1 mg in 1 mL ampule) injection based formula ~2 empty containers if applicable
 - 7) Arsenic Trioxide (1.0 mg/mL in 10mL ampules) injection based formula ~2 empty containers if applicable

8) Additional samples (up to 10% of sample population) to act as controls, ~4-10 containers

- Samples will be delivered to the University of California, Riverside (UCR) campus and custody will be transferred to Dr. Dan Schlenk, Dr. Jay Gan, or their representative(s) utilizing proper chain of custody protocol.

Sample Analysis

- Samples will be analyzed chemically. See opening paragraph and Table 1 in *UCR Budget Justification* for specific chemical sample methodology.
- Sample results will be identified and reported to the Department of Environmental Health in digital or hardcopy format.

Timeline

- Sample collection to be completed as samples become available, but no later than 90 days from date of grant fund approval.
- Sample analysis to be completed when samples are delivered to UCR, but no later than 180 days from date of grant fund approval.
- Sample analysis report to be completed and submitted to Riverside County Department of Environmental Health no later than 270 days from the date of grant fund approval.
- Samples report and/or results will be made available to the CUPA Forum Board and members as soon as they are technically reviewed and assessed for clarity.

Hazardous Waste P-Listed Pharmaceutical Container Study Projected Budget

Sample Analysis Cost

\$328.25 per sample (this includes labor, supply and analytical costs associated with analysis). See details in attached *UCR Budget Justification*.

The sample population is unknown, but approximately 80 container samples will be obtained.

That equates to \$26,260 ($\328.25×80).

Labor Costs

\$204 per hour is the cost rate of DEH staff in accordance with Riverside County Ordinance 640. A total projected 20 hours of DEH staff time will be spent on sample collection, delivery, UCR lab oversight, follow-up, and technical review of results.

This estimate equates to \$4,080.

Total Costs

\$30,340 (Figures reflect maximum sample population cost, incorporating the maximum amount of staff time).

The number of samples, and thus the greater applicability of the results State wide, depends on amount of funds granted. The Scope of Work can be adjusted as needed, or as determined by the CUPA Forum Board.

Expenditure	Rate	Cost
Sample Analysis	$\$328.25 \times 80$ samples	\$26,260
Labor-DEH	$\$204 \times 20$ hours	\$4,080
Total Cost		\$30,340

UCR Budget Justification

Detection of Warfarin and Nicotine from Packaging

For chemical residue measurements, each empty vial (warfarin) or packaging material (nicotine) will be extracted as described in Table 1 below.

Budget Justification

For chemical measurements associated with empty packaging and vials, \$328.25 per sample is required.

This **\$328.25 per sample cost** is based on:

Supplies

Solvents/reagents for chemical determination will cost **\$50 per sample**

Indirect Cost Rate

The UC-Riverside IDC for Sales/Service contracts is 31.3%--**\$78.25 per sample**

Personnel

Processing sample extraction would require approximately 20 hrs~ for one graduate students @ \$10/hr. per sample = **\$200 labor cost per sample**

Table 1. Extraction methodology for Warfarin and Nicotine from Vial and Packaging

	Nicotine	Warfarin
Extraction	extract with dichloromethane or acetonitrile (alkalinized with NaOH), then neutralize with HCl before evaporating the organic fraction	Extract with diethyl ether
HPLC condition	<p>Column: Hichrome 5C18 (150×4.6 mm, 5 μm) (Tomsic, Tokyo, Japan)</p> <p>Mobile phase: 7% methanol, 2 mM NaH₂PO₄, 0.2% phosphoric acid, and 1 mM heptane sulfonate sodium</p> <p>1 ml/min, 35 °C</p>	<p>Column: Agilent Eclipse XDB-CN (L10-USP) 150×4.6 mm, 5 μm</p> <p>Mobile phase: 32:68:1 ACN:Water:Glacial acetic acid</p> <p>1.5 ml/min, 25 °C</p>
Detection	<p>UV: 260 nm</p>	<p>Diode array detector (DAD): 260 nm</p>

Individual containers will be extracted by sonicating in a solvent (dichloromethane for nicotine and diethyl ether for warfarin) for 5 minutes, and the solvent extract will be dried under a gentle stream of nitrogen and re-dissolved in 5.0 ml methanol. An aliquot of 20 microliter (μL) will be injected into an Agilent 1100 Series high performance liquid chromatography (HPLC) for separation and detection. A UV detector operating at 260 nm will be used for the detection, and external calibration using standards with known concentrations will be used to quantification. A C18 column will be used for the separation, and the chromatographic conditions will be optimized through preliminary experiments. Solvent blanks, and duplicate samples will be analyzed to determine method performance. The relative standard deviation (RSD) will be controlled at <20% for duplicate samples. **The final results will be reported as mass per container, such as mg (nicotine)/container or mg (warfarin)/container.**