



March 19, 2009

**Drug Enforcement Administration
DEA Federal Register Representative/ODL
8701 Morrisette Drive
Springfield, VA 22152**

Subject: Docket No. DEA-316

MEMBER AGENCIES

- City of Cloverdale
- City of Cotati
- City of Healdsburg
- City of Rohnert Park
- City of Santa Rosa
- City of Ukiah
- County of Sonoma
- Sonoma County Water Agency
- Town of Windsor

DAVE RICHARDSON
Executive Director

300 Seminary Avenue
Ukiah, CA 95482
(707) 833-2553

Attn: DEA Federal Register Representative,

The Russian River Watershed Association (RRWA) is an association of local public agencies in the Russian River Watershed within Sonoma and Mendocino Counties (California) that have come together to coordinate regional programs for clean water, fisheries restoration, and watershed enhancement. For the past two years, RRWA has been partnering with local agencies, pharmacies and law enforcement offices to provide safe medicine disposal locations within the watershed.

To date, we have 30 drop-off locations that accept unwanted, expired, or unused medication in secure disposal bins during business hours. Currently, controlled substances are not accepted at pharmacies and can only be taken to police station locations. Our drop-off rates at police stations are very low compared to the amount of medication dropped off at pharmacies. We believe this is due to the location being an out-of-the-way stopping location to drop-off medicines (not the case with pharmacies), and the intimidating nature of entering the police station and handing over unused medication and controlled substances to a law officer behind bullet-proof glass.

We see very few controlled substances coming in to our disposal program and are concerned that by not allowing easy disposal for these substances, the general populous continues to throw these medications down the drain or into their household trash. As part of Docket No. DEA-316, the DEA is seeking input on providing more ways to safely dispose of dispensed controlled substances in a manner that is consistent with the Controlled Substances Act (CSA).

The CSA and DEA's regulations require that:

“persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA (unless exempt), keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.”

Currently,

“Reverse distributors are the only DEA registrants permitted to receive controlled substances from other registrants expressly for the purpose of disposal; other registrants, e.g., pharmacies, may dispose of controlled substances already in their possession that have expired, been damaged, or contaminated, but may not accept controlled substances from another person solely for the purpose of disposal.”

The DEA has asked reviewers to respond to a specific set of questions. After reviewing Docket No. DEA-316, RRWA has the following specific responses and has labeled them to be consistent with the question asked by the DEA.

State and Local Law Enforcement Agencies and Publicly Owned Treatment Works

18. ***Is the disposal of unwanted or outdated pharmaceuticals a problem in your area?*** Yes, prior to implementation of a regional take-back program, pharmaceuticals could only be disposed of at the Centralized Household Toxics Facility, and during limited one-day Safe Medicine Disposal Events.

19. ***Do individuals bring their unwanted or outdated pharmaceuticals including controlled substances which have been legally obtained, to your department for disposal?*** Yes, the Regional Safe Medicine Disposal Program sponsors 30 drop-off locations including 27 pharmacies and three police stations. Individuals bring in unwanted or unused medication for disposal. Only the police stations can receive controlled substances and these sites see much less disposal traffic than the pharmacy locations. We believe this is due to the location being an out-of-the-way stop to drop-off medicines and the intimidating nature of entering the police station and handing over unused medication and controlled substances to an officer behind a bullet-proof glass shield.

21. ***If individuals bring their unwanted or outdated pharmaceuticals including controlled substances which have been legally obtained, to your department for your department to dispose of, how does that process work? Do individuals drop the pharmaceuticals in a container, hand them to a department employee, or hand them to a law enforcement officer?*** For the police station locations, individuals hand medications to law enforcement officers or other staff at the counter. The officer or staff member then drops the medication into the disposal bin. For pharmacy locations, an individual either hands medications to the pharmacist to drop in the disposal bin, or removes medication from its original container and places the medication in the disposal bin under the supervision of the pharmacist.

31. ***Regardless of how you receive the medications for disposal, prior to disposal, where do you store these pharmaceuticals and under what security?*** Pharmaceuticals at local police stations are stored in secure bins behind the receiving desk in a secure room. Pharmaceuticals received at local pharmacy locations are stored in secure bins within the pharmacy behind receiving counters, and are only accessible by the Pharmacist during business hours.

32. ***How do you dispose of the controlled substances that you receive?*** A licensed medical waste hauler collects the medications when the bin is near full, depending on site traffic pick-ups occur between once a month to once a quarter.

33. ***What records do you generate regarding what you receive and what you dispose of?*** Currently, records of medications dropped-off are not kept by law enforcement or pharmacists. A chain of custody form is used for the bin disposal by the licensed medical waste hauler that picks up the medications for ultimate disposal. The medical waste hauler also tracks the total weight of each bin. Records could be kept by pharmacists should they be allowed to receive controlled substances at some point in the future. Although, some locations would probably choose to not participate if additional recordkeeping was required.

36. ***How much money has your participation in pharmaceutical disposal cost your department/facility in the previous year?*** The program is sponsored by local public agencies and therefore, drop-off locations have only been responsible for minimum coordination time in set-up of the disposal bins. The Regional Safe Medicine Disposal Program has spent approximately \$230,000 on outreach for the program, set-up and coordination of disposal locations, and hauling fees; \$200,000 of this was spent in the last year.

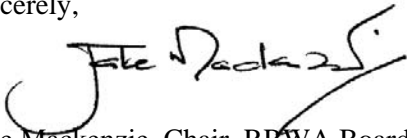
37. How many man-hours has your participation in drug disposal cost your department/facility in the previous year? The program is sponsored by local public agencies and therefore, drop-off locations have only been responsible for minimum coordination time in set-up of the disposal bins. The estimated number of hours needed to set-up and manage the program is approximately 550 hours. This does not include time spent by staff at drop-off locations.

38. If you are receiving unwanted or outdated pharmaceuticals for disposal, are you doing so as a result of local or State policy, law or regulation? The Regional Safe Medicine Disposal Program that was set up in Sonoma County and a portion of Mendocino County was put together and funded by local public agencies that are responsible for water delivery and wastewater treatment, and are concerned with the overall health of the watershed.

Overall, RRWA is appreciative that the DEA has been flexible in helping establish Pilot Safe Medicine Disposal Programs, however, RRWA would like to see an exception made for pharmacies to be able to accept controlled substances for disposal. Pharmacies are already DEA-registrants and pharmacists are familiar with the protocols in handling controlled substances. Records of controlled substances received for disposal could be maintained and disposal bins could be locked in the same safe as controlled substances after hours. We feel this exception is consistent with the CSA and its implementing regulations.

Thank you for your time in reviewing this request.

Sincerely,

A handwritten signature in black ink that reads "Jake Mackenzie". The signature is written in a cursive style with a large initial "J" and a long horizontal stroke at the end.

Jake Mackenzie, Chair, RRWA Board of Directors
Russian River Watershed Association, www.rrwatershed.org