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Colorado Department
of Public Health
and Environment

MEMORANDUM

Date: December 19, 2011

To: Health Care Facilities in Colorado

From: Joe Schieffelin, Program Manager
Solid and Hazardous Waste Program
Hazardous Materials and Waste Management Division

Subject: USEPA's 11/4/11 Memo: "Containers that Once Held P-listed Pharmaceuticals"

In a November 4, 2011 memorandum (attached), USEPA discussed the management of containers that once held P-listed hazardous waste. In particular, the USEPA memo states that, for pharmaceutical packaging (pill bottles, vials, blister packs, wrappers, etc.) that once held p-listed pharmaceuticals, it is only the weight of the residue, not the weight of the packaging that is counted toward the total waste generation rate. USEPA estimated that a 100-count bottle of 10-mg Coumadin (Warfarin) tablets contains about 1 mg of residue. USEPA also estimated that single dose packaging of p-listed pharmaceuticals contained about 35.8 ug (or 0.0358 mg) of P-listed residue. USEPA expects that if only the residue in the container is counted toward the generation rate, many health care facilities would be able to manage their hazardous waste as smaller category generators (conditionally exempt small quantity generators or small quantity generators).

The Solid and Hazardous Waste Program agrees with the USEPA's analysis. Therefore, in Colorado a health care facility may use actual or estimated weights of residues of p-listed waste on pharmaceutical containers, along with dispensing records or other data to determine the total amount of p-listed residue generated by a facility. The facility would then use these amounts to support a claim that it is a small quantity generator or a conditionally exempt small quantity generator. A health care facility should be prepared to demonstrate the basis of their estimated waste generation rates during hazardous waste inspections or upon request by the Hazardous Materials and Waste Management Division.

It is important to note that in Colorado, conditionally exempt small quantity generators must dispose of their conditionally exempt hazardous waste at an approved hazardous waste facility, as there are no solid waste landfills in the state that are authorized to take hazardous waste from conditionally exempt small quantity generators (6CCR 1007-3, Section 261.5(g)(3)). Therefore, the containers themselves, though their weight is not counted toward generator status, must be disposed at an authorized hazardous waste facility (assuming the containers have a residue of p-listed hazardous waste).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

NOV 4 2011

MEMORANDUM

SUBJECT: Containers that Once Held P-listed Pharmaceuticals

FROM: Suzanne Rudzinksi, Director
Office or Resource Conservation and Recovery

TO: RCRA Division Directors, EPA Regions 1-10

Issue

We have received numerous inquiries regarding the regulatory status of containers that once held pharmaceuticals that are on the "P-list" of commercial chemical products (CCPs) in 40 CFR 261.33(e). Most inquiries are regarding pill bottles that have held warfarin (brand names Coumadin and Jantoven; P001 at concentrations greater than 0.3%). But others have been about the packaging that held nicotine (P075) gum and patches and physostigmine (P204) ampoules. These inquiries are often about the original packaging for the P-listed pharmaceuticals – such as pill bottles, vials, blister packs, wrappers, etc. But they often extend to those containers that are used in healthcare facilities to deliver pharmaceuticals to patients – such as paper cups.

The inquiries have focused on the containers that held P-listed CCPs listed in 261.33(e) because P-listed CCPs are considered acute hazardous wastes when discarded. When a generator generates or accumulates more than 1 kg acute hazardous waste per month, the acute hazardous waste is subject to the large quantity generator (LQG) regulations of 40 CFR 262.34(a) (along with all applicable regulations in 40 CFR Parts 262 through 266, 268, 270 and 124, and notification requirements of section 3010 of RCRA). These generators have expressed concern that they are becoming LQGs, at least episodically, based on managing containers that have been fully dispensed and typically have very small amounts of residues in them which may not even be visually detectable.

Applicable Regulations

The regulatory status of CCP residues remaining in a container are specifically addressed in 40 CFR 261.33:

> "The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded…..
> (c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in §261.7(b)." [emphasis added]

According to 40 CFR 261.7(b)(3) there are three ways that a container that held an acute hazardous waste can be considered "empty":

> "A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§261.31 or 261.33(e) is empty if:
>
> (i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;
>
> (ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or
>
> (iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed."

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered "RCRA empty," even though the pharmaceutical may be fully dispensed. If the container is not "RCRA empty," then the *residues* are regulated as acute hazardous waste.

Three Approaches to the Issue that Generators Can Use

1. Count only the weight of the residue toward generator status

As the regulatory language makes clear, it is only the *residue* in the non-RCRA-empty container that is considered a P-listed hazardous waste; the container itself is not a hazardous waste. Accordingly, it is only the weight of the *residue* in the container that needs to be counted toward generator status; the weight of the *container* does not need to be counted toward generator status (see November 1983 Q&A; November 25, 1980, 45 FR 78527; and December 23, 1993 memo from Shapiro to Peter Joseph).

A major retail pharmacy that has raised this issue with EPA has provided some limited testing data. This generator has indicated that after all the pills have been dispensed from a 100-count bottle of 10-mg Coumadin pills, the bottle (without a cap) weighs approximately 10 grams. At 10 grams/bottle, the generator has calculated that 100 such bottles weigh 1000 g (or 1 kg/2.2 lbs), and if the pharmacy generates >1 kg/month, it would be an LQG for the month. However, the generator has also indicated that the same fully dispensed 100-count bottle of 10-mg Coumadin contains approximately 1 mg of residue (sometimes slightly higher or lower amounts) when all the pills have been dispensed. When only the 1 mg of *residue* is counted toward generator status, then it would take the combined residues from >1 million dispensed bottles to reach LQG quantities of >1 kg/month.

Becky Wehrman of SmartER Community Assistance has also provided some limited testing data. In this case, single-dose packaging was tested for several P-listed chemicals and the most residue that was detected was 35.8 µg (or 0.0358 mg).

It is important to note that it is hard to generalize these results to all containers that held pharmaceuticals. The data provided were for a few types of containers/packaging for a few of the most common doses of P-listed pharmaceuticals. Certainly not every generator will know the exact weight of residue in each container. However, using conservative approximations for similar situations of visually empty

containers, it is fair to say that it would take the combined residues from many thousands of containers before a generator would exceed the LQG quantities of 1 kg/month acute hazardous waste. For example, if a container had 100 mg of residue, it would take the combined residues from more than 10,000 containers to exceed 1 kg/month of acute hazardous waste.

In some cases, we anticipate that this interpretation will mean that some healthcare facilities that have been counting the weight of the container and therefore managing their hazardous waste in accordance with the LQG standards, will now be able to manage their hazardous waste in accordance with the CESQG standards of 40 CFR 261.5. In such instances, we are concerned that the containers, which could be discarded in the municipal wastestream, could be diverted from the municipal wastestream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. In order to prevent diversion, abuse, and identity theft of the containers and other packaging, CESQGs that discard containers that formerly held any pharmaceutical should destroy the containers prior to placing them in the trash (i.e.., by crushing the container in a trash compactor, and/or removing or defacing the labels).

In other cases, however, a healthcare facility may generate other acute hazardous wastes in a month that, combined with the P-listed container residues, would cause the facility to exceed the 1 kg monthly threshold. In such cases, all the acute hazardous wastes - including the pharmaceutical residues inside the non-RCRA-empty containers - would have to be managed in accordance with the LQG regulations. Among other requirements, the hazardous waste must be manifested to an interim status or permitted hazardous waste treatment, storage or disposal facility. The manifest only needs to reflect the weight of the hazardous waste; it does not need to include the weight of the containers. However, if only the total weight is known (i.e., weight of the hazardous waste residues plus the weight of the container), the total weight may be included on the manifest instead. Transporters typically charge on the basis of the total weight transported over a specified distance and; therefore, may choose to include the total weight of the shipment on the manifest (see March 4, 2005, 70 FR 10791; November 25, 1980, 45 FR 78527; and November 1983 Q&A). Weights that are listed on the manifest are often used by generators and inspectors to make estimations of generator status. If only the weight of the residues in a container is counted toward generator status, but the total weight is listed on the manifest, there could be some confusion about a generator's actual generator status. We recommend that when non-RCRA-empty containers are manifested, the generator/transporter use Box 14 of the manifest (Special Handling Instructions and Additional Information) to indicate that although the total weight is included on the manifest, the weight of the containers was not included in determining its generator status.

2. Demonstrate an equivalent removal method to render containers RCRA empty

Generators have been reluctant to use triple-rinsing to render their containers "RCRA empty" for several reasons. First, if a container that once held P-listed pharmaceuticals is triple-rinsed to render the container "RCRA empty," the rinsate would be considered P-listed hazardous waste due to the mixture rule (see 40 CFR 261.3(a)(2)(iv)), unless the P-listed CCP is listed for ignitability, corrosivity or reactivity and the rinsate does not exhibit the characteristic for which the P-listed chemical was listed (see 40 CFR 261.3(g)(1)). Second, although the container would be considered "RCRA empty" after triple rinsing, in most cases a generator would generate considerably more P-listed hazardous waste than it started out with. Finally, EPA strongly discourages the drain disposal of rinsate that is hazardous waste.

As a result, generators have been interested in demonstrating that the containers are "RCRA empty" in accordance with 261.7(b)(3)(ii), which allows a container that held an acute hazardous waste to be

considered "RCRA empty" if it has been cleaned by a method (other than triple rinsing) "that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal."

To our knowledge, there are no references in the scientific literature demonstrating an equivalent removal method to triple rinsing. In the absence of scientific literature, a generator would need test data to show that it has achieved an equivalent removal method. EPA has said in a memo dated July 28, 1993:

> "EPA requires no formal approval process if an alternative cleaning method is used to empty the container, and no variance is necessary under the federal regulations when using alternative cleaning methods pursuant to 40 CFR 261.7(b)(3)(ii). We would suggest that if you do use an alternative cleaning method, you document the method used and keep this record as part of your facility's operating record."

Therefore, in such cases, it would be up to the generator's implementing agency (i.e., the State or Region) to review a generator's data to make case-by-case decisions about whether the generator has achieved an equivalent removal method. The implementing agency could review data either at the generator's request, or during an inspection.

Finally, recently, generators have inquired whether a method such as "bag beating" would be an equivalent removal method to triple rinsing containers and other packaging that once held pharmaceuticals. This question stems from a May 20, 1985 memo, in which EPA stated that "beating the bags after emptying can be an alternative to triple rinsing," because paper bags cannot be triple rinsed. To our knowledge, containers and packaging that once held pharmaceuticals are, however, made of materials that, unlike paper bags, can be triple rinsed. Therefore, "bag beating" is an equivalent removal method to triple rinsing only for paper bags and not for other types of containers.

3. Show that warfarin concentration in the residue is below P-listed concentrations

The last approach only applies to pharmaceutical containers that once held the p-listed pharmaceutical warfarin (brand names Coumadin and Jantoven). Most of the inquiries we receive regarding pharmaceutical containers are about the P-listed pharmaceutical warfarin (brand names Coumadin and Jantoven). The P- & U-listings for warfarin are unusual in that they are concentration-based. Warfarin (and its salts) at a concentration of $> 0.3\%$ is listed as P001 in 40 CFR 261.33(e), while warfarin & salts at a concentration of $\leq 0.3\%$ is listed as U248 in 40 CFR 261.33(f). If the concentration of warfarin in the residue is ≤ 0.3 %, then the residue would meet the U248 listing, not the P001 listing. U-listed hazardous wastes are not acute hazardous wastes and are not subject to the 1 kg/month threshold.

We do not have, nor have we received, data regarding the concentration of warfarin in the residue remaining in fully dispensed containers of warfarin. Generators have indicated that some doses of warfarin pills contain concentrations high enough to meet the P-listing. But if a generator conducted analysis on the warfarin residues remaining in a fully dispensed container and the concentration of the residues is $\leq 0.3\%$ warfarin, then the residues would not meet the listing description for the P-listed waste, even if the pills originally in the container did meet the listing description. Instead, the residues remaining in the container would be regulated as U248 hazardous waste.

In order to determine the concentration of warfarin in the residue of fully dispensed Coumadin containers, one would need to conduct the following calculation:

$$\frac{\text{weight of the warfarin in the residue}}{\text{total weight of the residue remaining in the container}} \times 100 = \text{warfarin concentration of the residue (expressed as a percent)}$$

Additional Information

Please note that this letter discusses only the federal hazardous waste regulations. States that are authorized to implement the RCRA program may have regulations that are different than the federal regulations provided they are not less stringent than the federal program. Please consult your state regulatory requirements in addition to this memo. If you have any questions about the federal hazardous waste regulations discussed in this memo, please contact Kristin Fitzgerald at (703) 308-8286 or Fitzgerald.Kristin@epa.gov.

cc: RCRA Enforcement Managers, EPA Regions 1-10
RCRA Interpretive Network (RIN)
Dania Rodriguez, ASTSWMO