UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
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October 19, 2011

Mr. William Kulas
VISN 1 Environmental Program Manager
1 VA Medical Center
Togus, ME 04330

Re: 402/00SH – Empty Coumadin Container Interpretation (warfarin stock bottles)

Dear Mr. Kulas:

Thank you for your recent inquiry dated August 10, 2011 regarding specific questions related to the management of Coumadin (warfarin) stock bottles (i.e., containers) at various VA facilities throughout New England. The purpose of this letter is to address your questions and provide additional guidance regarding your specific concerns.

As background, in order for materials to be classified as hazardous wastes under the Resource Conservation and Recovery Act (RCRA), they must first be a solid waste. Materials become solid waste when they are discarded or are intended for discard (see 40 CFR 261.2). They become hazardous waste if they are "listed" in 40 CFR Part 261, Subpart D, or if they exhibit one or more of the hazardous waste characteristics in 40 CFR Part 261, Subpart C. In accordance with 40 CFR 261.33(e), Coumadin is a commercial chemical product (CCP) formulation with warfarin as the sole active ingredient. At concentrations greater than 0.3%, it is considered a P-listed (acutely hazardous) waste when it is discarded or intended to be discarded and carries the waste code P001. (Note, warfarin at concentrations of 0.3% or less are not considered acutely hazardous wastes and carry the waste code U248).

The following is EPA Region 1's position in response to your specific questions and concerns.

1. Should empty Coumadin stock bottles be managed as hazardous waste?

Yes, if the containers are not "RCRA empty" in accordance with 40 CFR 261.7(b), the residues remaining in the containers (as well as the containers) must be managed as hazardous waste.

You correctly state in your letter that the scope of the P- and U-listings in 40 CFR 261.33 relates to chemicals that have not been used. In accordance with 54 FR 31335-31336, July 28, 1989 which was referenced in your letter, a P- or U-listed chemical (i.e., a commercial chemical product formulation with a sole active ingredient, such as warfarin), when it has been used for its intended purpose, would no longer maintain the P- or U-listing. However, in the particular scenario you describe, where all the Coumadin (warfarin) tablets in a stock bottle/container have been used or dispensed, there is likely residue, from the tablets, remaining in the bottle. Residue remaining in a container would not have been used for its intended purpose. Thus, per 40 CFR 261.33(c), the residue remaining in a container when discarded or intended for discard would be considered either a P001 or U248 listed waste as applicable unless or until the container is determined to be "RCRA

empty" pursuant to the requirements of 40 CFR 261.7(b). Only if and when these "RCRA empty" requirements are met may the container be managed as a non-hazardous solid waste.

We understand triple rinsing may not be feasible in certain settings. In such circumstances, the residues, as well as the bottle/container, should be handled as either a P- or U-listed waste as applicable. Additional information relating to the management of these items is provided in answers to questions 2 and 3 below.

Also, you raised a concern which relates to language in EPA's proposed Universal Waste Rule for Pharmaceuticals (specifically, footnote 30) in which there is no distinction drawn between the management of a container/bottle from which all the P- or U-listed tablets have been dispensed (but not "RCRA empty") versus a container/bottle containing P- or U-listed tablets to be discarded. This is because both containers/bottles contain wastes or residues which have not been used for their intended purpose and, therefore, would be subject to P or U-listed waste management requirements unless or until they meet the "RCRA empty" requirements pursuant to 40 CFR 261.7(b). See 54 FR 31335-31336, July 28, 1989 and 40 CFR 261.33(c).

Also, we are aware that guidance relating to the disposal of pharmaceutical containers and packaging varies among state hazardous waste programs. Under section 3006 of RCRA, EPA Regions authorize provisions of state hazardous waste programs to be in effect in lieu of analogous federal ones. As such, authorized state programs have the authority to make regulatory determinations as needed in their state. Also, states may choose to be more stringent in their regulations and policies than the analogous federal requirements. We work with our States to try to ensure that any State interpretations are not less stringent than federal interpretations.

In regards to a recent EPA interpretation by EPA Region 1 to David Gamblin at the Holyoke Medical Center, you ask if the excerpted language noted on page 2 of EPA's letter would apply to stock pill bottles and containers. We quoted a Massachusetts State interpretation that certain items such as foil/blister packs and paper/plastic cups that held wafarin tablets do not need to be managed as non-empty containers holding listed wastes provided that there is no visible residue on such items. The answer to your question is no; we do not support or believe that the logic of that State interpretation was intended to include items such as pill bottles that clearly are containers. Also, the questions that were raised by Holyoke Medical Center relative to the management of certain pharmaceutical packaging (i.e., wrappers and blister packs from used nicotine and warfarin products) are currently being evaluated by EPA Headquarters which may result in HQ issuing related guidance. Until such time as HQ issues relevant guidance and in order to provide a timely answer to a regulated entity in need of a decision, Region 1 decided not to make an EPA interpretation, but to defer to the authorized state agency's policy in the interim. Although our response includes excerpted language from the state's relevant guidance to which we deferred, we were not necessarily embracing the statements as EPA policy.

2. Is the weight of the Coumadin stock bottle or only the warfarin residue therein counted toward monthly generator status.

Only the warfarin residue is counted towards the monthly generator status.

According to the EPA guidance document referenced in your letter, RCRA Online #12151, as well as 45 FR 78527, November 25, 1980, the amount of waste a generator uses to calculate his or her generator status does not include the container – it is only the material or residue in the container that the agency intends to regulate. This logic would apply to the Coumadin/warfarin stock bottle scenario you describe in which fully dispensed bottles are being disposed of as hazardous wastes due to the residue content. As such, only the weight of the residues contained in the bottle would be required to be counted towards the monthly generator status; the weight of the bottle itself does not need to be counted. However, both the bottle and the warfarin residue, remaining within, are required to be handled as hazardous wastes unless the bottle can be determined "RCRA empty" in

accordance with 40 CFR 261.7(b). See the Monthly Call Center Report Question, November 1983, RCRA Online #12151; and 45 FR 78527, November 25, 1980 (attached).

In order to determine the amount of P-listed hazardous waste or residue remaining in empty stock bottles for the purpose of monthly generator status determinations, the generator would need to develop a process by which the amount of waste or residue remaining in such bottles can be accurately and readily determined. The process should adequately address how the amounts of waste or residue from different-size bottles/containers of specific P-listed hazardous waste and form (e.g., powder, liquid, or semi solid, etc.) is determined so that the amount of waste residues generated from collected bottles/containers, possibly of various sizes, can be readily determined. The process should enable those managing the wastes to be able to assess how much P-listed residue/waste has been generated at any given time to ensure that accurate monthly generator status calculations are made. This is especially important with regard to the Conditionally Exempt Small Quantity Generator (CESQG) and Small Quantity Generator (SQG) one-kilogram generation and accumulation thresholds for P-listed acutely hazardous wastes. Exceeding such thresholds subjects these generators to the large quantity generator requirements. Documentation of such a process should be maintained onsite. Large and small quantity generators must maintain such records.

3. Is the volume of the Coumadin stock bottle or only the warfarin residue therein counted toward the one-quart limit for acutely hazardous waste at a satellite accumulation area?

The one-quart accumulation limit of acutely hazardous waste in a satellite area applies to the hazardous waste residues accumulated and not the container. See 45 FR 78527, November 25, 1980, attached.

As explained above, it is the residues within a container that the agency intends to regulate. As such, a generator would need to be able to determine the volume of P-listed waste residues remaining in empty stock bottles/containers collected in a satellite accumulation area. Similar to the protocol discussed in item 2 above, the generator would need to develop a process by which the amount of remaining waste or residue in bottles/containers can be accurately and readily determined. The process should enable those in control of wastes in the satellite accumulation area to be able to assess the quantity of waste accumulated at any given time so as to ensure the amount of waste and residues accumulated do not exceed the one-quart satellite accumulation limit (i.e., volumetric equivalent of one kilogram). Again, this is especially important as exceeding the one-quart limit will subject generators to additional requirements. Documentation of such a process should be maintained onsite. Large and small quantity generators must maintain such records.

Finally, as previously mentioned, under section 3006 of RCRA, EPA authorizes state hazardous waste programs and section 3009 of RCRA allows authorized States to be more stringent in their regulations and interpretations. Since all six New England States have been authorized, you should check with the environmental agencies in those states in which the VA has facilities that are subject to RCRA regulations for their position in matters discussed above.

Also, please be aware that EPA Headquarters is currently evaluating certain aspects of the management of hazardous pharmaceutical wastes in a healthcare setting that may relate to questions that were raised in your letter. Should guidance issued by Headquarters address the issues covered by the guidance we are providing today, we would update our guidance

If you have any questions about today's regulatory interpretation, please contact Robin Biscaia of my staff at 617-918-1642.

Sincerely,

Mary Sanderson, Chief
Remediation and Restoration II Branch
Office of Site Remediation and Restoration (OSRR07-2)

Enclosure

cc: Beth Deabay
Anne Fenn

health and the environment because residues that remained in empty containers would be unregulated. It would require facilities about which EPA is most concerned, i.e., those container cleaning facilities which accumulate large amounts of container residues, to properly manage the residues as hazardous wastes once they were removed from the container. EPA would consider the person who removed the waste to be the generator. Persons who removed only small quantities of residues could qualify for the small quantity generator exclusion, if they also did not have large quantities of other hazardous wastes. One problem with this approach, though, would be how persons removing residues from empty containers that had been shipped to them would receive notice that the residues were hazardous wastes because, until their removal, the residues would be unregulated, and thus could be shipped without a manifest while they remained in their containers.

3. *Limitation on the amount of unregulated residue.* A third option EPA is considering is to regulate only persons who handle large amounts of hazardous waste residue in, or removed from, empty containers. The Agency could accomplish this by limiting the amounts of unregulated residue a person could manage during a particular period of time without becoming subject to hazardous waste management controls. All container residues handled by persons who regularly deal with large amounts of such residues could be regulated.

EPA solicits comments and data on whether the residues left unregulated by § 261.7 may pose a substantial hazard to human health or the environment and, if so, whether commenters favor one of the three options outlined above, or some other alternative to deal with the problem.

V. Clarification of 40 CFR 261.33

Section 261.33(c) lists containers that hold residues of certain acutely hazardous commercial chemical products, manufacturing chemical intermediates, and off-specification products as hazardous wastes if and when they are discarded or intended to be discarded. EPA is making certain clarifying changes to this section.

A. Clarifying Changes Including Regulation of Residues Rather Than Containers

First, as mentioned above, today's amendments move the provisions of § 261.33(c)(1)–(3) to § 261.7(b). Second, EPA also is changing the remaining wording of § 261.33(c) and the title of § 261.33 to clarify that it is the hazardous material residue in a container, rather than the container itself, that is controlled under the regulations if and when the residue is discarded or intended to be discarded. This avoids the problems that can result from a literal reading of the regulations if the container, rather than the residue, is considered a hazardous waste. Read literally, for example, § 262.34(a) would require that a container, if the container itself were considered a hazardous waste, be placed within another container for temporary accumulation.

This change to the wording of § 261.33(c), although merely a clarification of the Agency's intent in the May 19, 1980, regulations, does alter the substance of the requirement in one respect. Although § 261.33(a) implies that any amount of a listed acutely hazardous material is a hazardous waste when it is discarded or intended to be discarded, § 261.33(c) in the May 19 regulations implies that a container or liner that previously held an acutely hazardous material listed in § 261.33(e) becomes a hazardous waste only if and when the container or liner—as opposed to the hazardous waste residue—is "discarded or intended to be discarded." Under one reasonable interpretation of § 261.33(c), a container which is re-used by anyone or sent to a reconditioner for cleaning and subsequent re-use would not be subject to the hazardous waste management regulations because it was not "intended to be discarded." When the residue, rather than the container, is considered the hazardous waste, as it is under the amended § 261.33(c), a container holding a regulated residue, i.e., a container that is not "empty," that is sent to a reconditioner for cleaning and re-use must be accompanied by a manifest and may only be sent to a person with a RCRA permit or interim status for the treatment, storage or disposal of the waste in question. Because this amendment to § 261.33(c) may extend regulatory control to some persons whose activities were not previously regulated under RCRA, EPA is providing time for these persons to notify under Section 3010 of RCRA and to submit permit applications pursuant to 40 CFR Part 122. See the discussion above in section II of this preamble entitled "Compliance Dates."

On the other hand, if the residue of an acutely hazardous waste listed in § 261.33 itself is to be beneficially used, re-used, recycled or reclaimed, it is not being discarded and it never becomes a hazardous waste and thus is not subject to the hazardous waste management regulations. For example, if a container that has held an acutely hazardous material listed in § 261.33(e) is to be re-used to contain the same material listed in § 261.33(e) that it previously held (and the initial residue is not discarded), or to contain some other material where the mixing of the other material with the residue of the § 261.33(e) material constitutes a beneficial use or re-use of that residue, then the acutely hazardous residue in the container or liner is not discarded and thus is not a hazardous waste. EPA has added a "comment" to § 261.33(c) to remind readers of the regulation that unless residues are beneficially used or re-used, or legitimately recycled or reclaimed, or are being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard and thus a hazardous waste.

B. Interim Final Promulgation

EPA believes that use of advance notice and comment procedures for the clarification to § 261.33(c) would be impracticable and contrary to the public interest, and therefore finds that good cause exists for adopting this change in interim final form (see 5 U.S.C. 553(b)(B)). Delay in promulgating this clarification could cause significant harm to the regulated community and the general public. Without this clarification, confusion exists over whether the provisions of § 261.33(a) or § 261.33(c) govern container residues of acutely hazardous materials that are discarded or intended to be discarded. EPA intended that all such residues be controlled as hazardous wastes, but, as discussed above, one reasonable interpretation of § 261.33(c) is that such residues are not considered hazardous wastes if the containers that hold such residues are not discarded. To give notice to the regulated community of how EPA intended § 261.33(c) to work, and to protect the public against the possible mismanagment of the acutely hazardous material residues that may remain in unrinsed containers that are re-used, EPA is promulgating its clarification to § 261.33(c) in interim final form. EPA will accept comments on this change for 90 days and will make any further changes deemed necessary as a result of those comments.

C. Effective Date

Section 3010(b) of RCRA provides that EPA's hazardous waste regulations and revisions thereto take effect six months after their promulgation. The purpose of this requirement is to allow persons handling hazardous wastes sufficient lead time to prepare to comply with major new regulatory requirements. EPA