



Department of Toxic Substances Control

Matthew Rodriguez
Secretary for
Environmental Protection

Barbara A. Lee, Director
1001 "I" Street
P.O. Box 806
Sacramento, California 95812-0806

Edmund G. Brown Jr.
Governor

December 24, 2015

Ms. Charlotte A. Smith, R. Ph., M.S.
Senior Regulatory Advisor
WMSS PharmEcology Services
1650 North 121st Street
Wauwatosa, Wisconsin 53226

P-LISTED, RCRA HAZARDOUS WASTE CONTAINERS AT CALIFORNIA HEALTHCARE FACILITIES

Dear Ms. Smith:

This letter is in response to your questions and the ongoing discussion to the Department of Toxic Substances Control (DTCS) regarding the regulatory status of California healthcare facilities that generate pharmaceutical-related wastes classified as RCRA hazardous wastes. Specifically, you have asked DTSC if California generators can follow US Environmental Protection Agency's (US EPA) guidance as set forth in the November 4, 2011 letter by: (1) Considering only the weight of the RCRA P-listed hazardous waste residues when determining their generator status; and (2) Entering only the mass of the P-listed RCRA hazardous waste residue (i.e., exclude the masses of the containers) when completing hazardous waste manifests.

Background

Many healthcare facilities discard containers that are identified as RCRA P-listed hazardous wastes (e.g., container residues of the pharmaceuticals warfarin and nicotine). Under federal and State regulations, these containers are "not empty" unless they have been triple rinsed or cleaned using another method that has been demonstrated to be equivalently effective. Hence, these container residues are not exempt from regulation as hazardous wastes.

Pursuant to California regulations, the container residues as well as the containers themselves must be managed as hazardous wastes when disposed.

On November 4, 2011, US EPA issued a letter titled, "*Containers that Once Held P-listed Pharmaceuticals*" (enclosed). The letter clarified that, per federal RCRA regulations, only the mass of the P-listed residue in the container is hazardous waste and therefore included in the hazardous waste monthly generation total ("counts"). (Counts are used by a healthcare facility to determine its status as a conditionally

exempt, small, or large quantity generator.) The letter further stated that the mass of the container itself need not be included in the monthly generation total. As a result, the guidance provided in the November 4, 2011 letter may enable some healthcare facilities to remain below the 1 kg monthly total acute hazardous wastes threshold.

Status of the Waste under California State Law

California adopted the federal regulations identifying RCRA P-listed, hazardous waste container residues. Specifically, the California Code of Regulations, title 22, section 66261.33 states the following:

"The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded as described in section 66261.2(b):

(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 subsections (e) or (f) of this section, unless the container is empty as defined in section 66261.7(d) of this chapter." (Emphasis added.) (Cal. Code Regs., tit. 22, § 66261.33, subd. (c).)"

However, California's regulation differs from its federal counterpart. The distinction between the regulations is that the federal regulation specifically addresses the residue "Residues of hazardous waste in empty containers" (40 C.F.R. § 261.7) and California's regulation addresses the "Contaminated Containers" as whole entities "Contaminated Container" (Cal. Code of Regs., tit. 22 § 66261.7). Specifically, California Code of Regulations, title 22, section 66261.7, subdivision (r) states:

"(r) Any container, or inner liner removed from a container, which previously held a hazardous material, including but not limited to hazardous waste, and which is not empty as defined in subsection [...] (d) of this section, . . . shall be managed as a hazardous waste in accordance with this division and Chapter 6.5 of Division 20 of the Health and Safety Code (commencing with Section 25100)." (Emphasis added.)

California regulations require that the hazardous waste residue and its container be managed as hazardous wastes. Although, under the federal regulations, technically speaking, only the residues are identified as a RCRA P-listed hazardous waste. California regulations are consistent with US EPA's June 16, 1987 RCRA letter titled "Containers Used to Hold Listed Chemotherapy Drugs" (enclosed). The letter was in response to whether the weight of the "empty vial" should be included in determining the amount of drug residues to be disposed. In this letter, US EPA replied that:

"Under EPA regulations governing the management of hazardous wastes, any container used to hold these chemicals (such as vials) are considered hazardous wastes unless these containers meet the criteria of an "empty container."
... Agency recommended that the entire volume of waste be weighed..."

When DTSC observes a hazardous waste that is comprised of non-empty containers having RCRA P-listed hazardous waste residues inside them, DTSC considers the entire container and residue combination as "the hazardous waste" that must be properly managed to protect human health and the environment. Accordingly, generators must include the weight of the container and not just the mass of container residue when computing the amount of acute hazardous waste generated (i.e. handling each residue and its associated container as a whole entity of hazardous waste). (Cal. Code Regs., tit. 22, § 66261.100, subd. (a)(2).)

Conclusion

California regulations are similar to the federal regulations in that it considers RCRA P-listed hazardous waste residue remaining in a container to be hazardous waste. However, California regulations differ from the federal approach in that California considers the non-empty containers as whole entities (i.e., the "Contaminated Containers") which are hazardous wastes.

Therefore, faced with two conflicting US EPA RCRA guidance letters the June 16, 1987 and the November 4, 2011, DTSC concludes that it would be inappropriate to allow California healthcare facilities (generators) to apply the relaxed guidance provided in US EPA's November 4, 2011 letter to the RCRA P-listed hazardous waste residues and containers and to simultaneously continue to follow US EPA's more stringent guidance (June 16, 1987 letter) for the possibly less toxic hazardous waste residues when determining the generator status of their facilities in California. California's regulations are more stringent than US EPA's in this respect. Therefore, at this time, as US EPA's most recent guidance on this issue is inconsistent with California's regulations, DTSC concludes it will continue to use US EPA's previous guidance (as DTSC has been doing for many years), not the guidance provided in US EPA's November 4, 2011 letter.

DTSC may revisit this issue when US EPA's new rules for pharmaceutical wastes are promulgated. As such, California healthcare facilities should include the total weight (of the container and the residues) on the hazardous waste manifests. This weight will count toward the monthly total to determine if the healthcare facility meets the 1 kg per month threshold for acute hazardous wastes. The generator must enter the total weight of the container and residue of the RCRA P-listed hazardous waste on the Uniform Hazardous Waste Manifest. Healthcare facilities should be aware that DTSC will use the weight of the container and residue to calculate tonnages and collecting annual Generator Fees.

Ms. Charlotte A. Smith, R. Ph., M.S
December 24, 2015
Page 4

Thank you for your questions regarding the regulatory status of healthcare facilities located in California that generate *container-wastes* that are P-listed RCRA hazardous wastes. I hope this information is helpful. Please contact Mr. Kevin Sanchez, of my staff, at 916-322-8677 or at Kevin.Sanchez@dtsc.ca.gov if you have further questions or concerns.

Sincerely,



Charles Corcoran, Chief
Industry Assistance Training and Outreach Unit
Policy Implementation and Support Branch
Policy Program and Support Division
Hazardous Waste Management Program
Department of Toxic Substances Control

cc: Keith Kihara, Chief
Enforcement and Emergency Response Division
Hazardous Waste Management Program
Department of Toxic Substances Control
1001 I Street, 11th Floor
P.O. Box 806
Sacramento, CA 95812-0806

Pauline Batarseh, Chief
Policy Implementation and Support Branch
Policy Program and Support Division
Hazardous Waste Management Program
Department of Toxic Substances Control
1001 I Street, 11th Floor
P.O. Box 806
Sacramento, CA 95812-0806

Maria Soria, Chief
Berkeley Enforcement and State Oversight Branch
Enforcement and Emergency Response Division
Hazardous Waste Management Program
Department of Toxic Substances Control
700 Heinz Avenue
Berkeley, California 94710-2721

Ms. Charlotte A. Smith, R. Ph., M.S
December 24, 2015
Page 5

cc: Denise Tsuji, Chief
Emergency Response (Sacramento) and Sacramento Enforcement Branch
Enforcement and Emergency Response Division
Hazardous Waste Management Program
Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, CA 95826

Kevin Sanchez
Sr. Environmental Scientist (Specialist)
Industry Assistance Training and Outreach Unit
Policy Program and Support Division
Hazardous Waste Management Program
Department of Toxic Substances Control
1001 I Street, 11th Floor
P.O. Box 806
Sacramento, CA 95812-0806

Jay Cross, Attorney
Office of Legal Affairs
Department of Toxic Substances Control
1001 I Street, 23rd Floor
P.O. Box 806
Sacramento, CA 95812-0806

9441.1987(45)

CONTAINERS USED TO HOLD LISTED CHEMOTHERAPY DRUGS

JUN 16 1987

Mr. Fred Kamienny
Vice President
PRN Service, Inc.
1210 Morse
Royal Oak, Michigan 48067

Dear Mr Kamienny:

This responds to your letter of April 13, 1987, regarding the regulatory status of chemotherapy drugs and related supplies. In particular, you questioned whether the weight of the "empty" vial should be included in determining the amount of drug residues to be disposed.

As you pointed out, several chemotherapy drugs are listed in 40 CFR 261.33(f) (commonly known as the U-list). As such, these wastes are regulated under the EPA hazardous wastes regulations (unless subject to the small quantity generator exclusion). Included in the listing are the following discarded commercial chemical products, off-specification species, container residues, and spill residues:

- 1) chlorambucil (U035)
- 2) cyclophosphamide (U058)
- 3) daunomycin (U059)
- 4) melphalan (U150)
- 5) mitomycin C (U010)
- 6) streptozotocin (U206)
- 7) uracil mustard (U237)

Under EPA regulations governing the management of hazardous wastes, any container used to hold these chemicals (such as vials) are considered hazardous wastes unless these containers meet the criteria of an "empty container." Under the empty container provisions such vials are excluded from regulation if the material has been removed by pouring, pumping, and aspirating, and no more than 1 inch of residue remains in the bottom of the vial or no more than 3 percent by weight of the total capacity of the container remains in the container. (See 40 CFR 261.7)

RO 12946

The Agency is aware, however, that prudent practice dictates that materials contaminated with these chemicals (such as syringes, vials, gloves, gowns, aprons, etc.) not be handled after use. Therefore, to minimize exposure to these toxic chemicals, the

Agency recommends that the entire volume of waste be weighed and that there be no attempt to remove any residue from the vial before disposal.

Chemotherapy drugs that are not listed hazardous wastes are not regulated by EPA. However you should contact your State or local government regarding the management of these chemicals. Also, the National Institutes of Health (NIH) provides guidance on handling and management of antineoplastics. Contact Harvey Rogers, at NIH for further information. Mr. Rogers may be reached at (301) 496-7775.

If you should have any further questions regarding regulatory requirements for specific wastes, you may call RCRA Hotline at (800) 424-9346, or contact Mitch Kidwell, of my staff, at (202) 382-4805.

Sincerely,

Jacqueline W. Sales, Chief
Regulation Development Section



Matthew Rodriguez
Secretary for
Environmental Protection



Department of Toxic Substances Control

Barbara A. Lee, Director
1001 "I" Street
P.O. Box 806
Sacramento, California 95812-0806



Edmund G. Brown Jr.
Governor

HAZARDOUS WASTE PHARMACEUTICALS RULE COMMENTS

I. General Comments of Structure of the Proposal

EPA has proposed a set of alternative management rules for pharmaceuticals for some persons, but not all persons who manage hazardous waste pharmaceuticals under RCRA. EPA has chosen to place these standards in 40 CFR part 266. Historically EPA has used part 266 for recyclable materials and, more specifically for materials that are subject to less than full hazardous waste regulatory standards because some form of recycling or resource recovery was occurring. Most current 40 CFR part 266 standards provide rules that are less stringent than the traditional hazardous waste generator and facility standards. However, EPA has decided the proposed rules are more stringent standards for generators of hazardous waste pharmaceuticals. EPA's placement of these standards in part 266 seems to deviate from its past practices and appears to be incongruous with most regulators' understandings of EPA's regulatory schema. EPA's proposal to place these standards in Part 266 (not the standards themselves, but their placement) is very confusing. After reviewing the proposal, it appears that EPA has made the following decisions:

- handlers of hazardous waste pharmaceuticals should be regulated largely as generators
- "reverse distributors" is a misnomer
- only minimal, if any recycling, reuse or resource recovery is occurring via "reverse distribution,"
- a more stringent set of rules is required for hazardous waste pharmaceuticals and their generators.

DTSC concludes that EPA should consider an entirely different schema for the proposed rule. The outline of the proposed rule should be based on the following general comments which serve to create two sets of generator standards for these persons (generators). Further elaboration on these general comments may be found in the specific comments section below.

Inasmuch as EPA admits in the preamble, reverse distributorship is (and has been) a fiction for too long. As EPA describes in the preamble, these entities are really an extension of the primary generator; in most cases, a "secondary generator". Therefore, DTSC recommends EPA adopt a regulatory schema, patterned after the Generator Improvements Proposed Rule that places one set of standard each for the two entities; Primary and Secondary Generators of Pharmaceuticals. In Part 262,

Standards Applicable to Generators of Hazardous Wastes, which are entitled Standards for Primary and Standards for Secondary, Generators of Hazardous Waste Pharmaceuticals, would appear as:

- Standards for VSQGs
- Standards for SQGs
- Standards for LQGs
- Standards for Primary Generators of Pharmaceuticals, including Healthcare, Retail and Pharmaceutical Manufacturing and Distributing generators, (i.e., all who would send pharmaceutical wastes to these “secondary generator” entities)
- Standards for Secondary Generators of Hazardous Waste Pharmaceuticals.

In conjunction with the above, DTSC would recommend that EPA then place the definition of pharmaceutical in 40 CFR 260.10 and would amend 40 CFR 261.2 to define, as solid waste, “any *pharmaceutical*, as defined, that, in addition to the above methods of discard, is sent to a Secondary Generator of Hazardous Waste Pharmaceuticals.” The applicability sections of Part 262 would, of course, direct all primary generators to follow a single set of standards for their ordinary hazardous wastes (as either a VSQG, SQG, or LQG) and the tailored Standards for Primary Generators of Pharmaceuticals for their pharmaceutical wastes (proposed 40 CFR 266.503 -.507, as applicable). The latter would not count toward the ordinary hazardous waste generator status. However, the regulations could provide the option to follow either the applicable full hazardous waste rules or the (new) tailored rules. EPA’s proposed 40 CFR “Reverse Distributor” Standards would be contained in the *Standards for Secondary Generators of Hazardous Waste Pharmaceuticals* section; however, with changes from the proposal to remove the *potentially creditable* and *non-creditable labels* categorization issues (see elaboration below), and (to remove) “is it a waste or not confusion” (it all is), and most importantly to end the *reverse distribution/reuse* fiction for good.

DTSC recommends EPA eliminate the definitions of *potentially creditable* and *non-creditable hazardous waste pharmaceuticals*. Simply put, as EPA has defined these terms, no person can visually discern, nor determine, the difference between one or more hazardous waste pharmaceuticals and tell which definition applies. However, EPA has defined a workable schema with regard to its proposed definition “Evaluated Hazardous Waste Pharmaceutical” and only needs to also define “Unevaluated Waste Pharmaceutical” and a regulatory standard that provides a means to distinguish the two and to complete a workable structure, around which EPA can attach most (if not all) of its proposed management standards for hazardous waste pharmaceuticals.

California, other states and EPA have all dealt with part 266 subpart F unobservable and unenforceable standard of “economically significant amounts.” DTSC recommends that EPA recognize such standards are not practicable regulatory waste management standards and, especially in this context, where no significant recovery or reuse is occurring, are unwarranted. DTSC asks EPA to not unnecessarily confuse the regulations with issues of business credit. DTSC asks EPA to adopt a set of clear

waste management standards that ensures the safe handling of hazardous waste pharmaceuticals (creditable or not) that can be applied and enforced without, unobservable, unmeasurable economic variables that have no relevance to the safe handling of the hazardous wastes.

DTSC believes its proposal herein makes this possible while not making credit and other issues of business part of the hazardous waste regulatory standards. DTSC urges EPA to revise its proposal to incorporate a simpler perspective. DTSC suggest EPA address the following questions:

- What are the necessary waste handling standards?
- Can businesses evaluate materials for credit (or not)?
- May businesses conduct such transactions (as well as other business transactions) while complying with these waste handling standards?
-

DTSC asks EPA to re-examine its proposed rule from this simpler perspective.

Under this revised schema, the Primary Generators (i.e., hospital, doctor's office, LTCF, or retailer, etc.) would send the waste pharmaceuticals, in accordance with EPA's proposed standards, to the Secondary Generators for "evaluation". (Unlike EPA's use of the word, the *evaluation* is the completion of the generator's hazardous waste determination – not a business evaluation of credit or some other business concern.)

The Primary Generator standards would be largely the proposed part 266.502/503 standards combined. However, the shipments could/would include both hazardous and non-hazardous pharmaceuticals as long as they were in: 1) un-opened, 2) original packaging, and 3) largely intact packaging. This regulatory standard will clearly set the scope of which hazardous waste pharmaceuticals primary generators (retailers and healthcare and research facilities, etc.) may send to Secondary Generators. DTSC proposes EPA add a labeling requirement with an EPA-specified, color-coded (e.g., orange) label containing the words (Primary sent: date).

The Secondary Generators would then complete the *evaluations* and would apply either: 1) an EPA-specified (color-coded) label with date, for an Evaluated Hazardous Waste Pharmaceutical, or 2) another EPA-specified second e.g., orange label (symbolizing moving forward for evaluation) containing the words (R.D. sent: date). In this system, there would be one set of standards for all Primary Pharmaceuticals Waste Generators and for all Secondary Generators who send pharmaceutical hazardous wastes forward for evaluation. These would be duplicative and appear in both of the new part 262 sections.

There would also be one set of rules for all "evaluated hazardous waste pharmaceuticals" (i.e., for those wastes for which the hazardous waste determinations were completed) for all generators. Only hazardous waste pharmaceuticals meeting the unused, unopened, original packaging standard would be eligible for moving forward to evaluation. Any other "hazardous waste pharmaceuticals," e.g. used IV

bags with residues would be exactly that "hazardous wastes!" (These *non-creditable hazardous waste pharmaceuticals* - a definition that says/does nothing would not fall under any other confusing definition. If they did not meet the standard as eligible for sending forward for evaluation, these hazardous wastes would be regulated at the primary generators site and would be sent to TSDFs using a manifest, but they may get the benefit of alternate waste counting rules, alternate accumulation time limits, etc.

DTSC recommends that EPA address the following:

- Codify the Controlled Substances provision in either 40 CFR 261.4(a)(next number) or in new (g),
- EPA codify the Prohibition of Sewering (proposed 266.503) in each of the applicable sections.
- Re-locate the various more universal proposed empty-container provisions (266.507) into one or more new subsections in 40 CFR 261.7.

DTSC believes other generators, such as research laboratories, Universities, R&D facilities, etc. may have an equivalent need for these the above provisions. For example, if a manufacturing facility administers an injection or a pill of a finished pharmaceutical product to a test animal as part of its product testing protocol, would the fully dispensed syringe or blister pack be any less likely to qualify for, or any less deserving of, the empty container exemption? Likewise, are there not circumstances where freeing controlled substance hazardous wastes from RCRA constraints (when managed under DEA's safeguards)? As with the discussion above, if the waste management standards are relevant to the waste and are protective, then why limit them to one, two, or a few industry sectors?

In summary, DTSC believes that EPA can better implement its proposed rule by placing almost all of the proposed provisions in The Standards for Generators, along with what the Agency is doing in its Generator Improvements Rule. Codification in part 262 will better clarify for all generators of waste pharmaceuticals (not just healthcare sector parties) that some pharmaceutical hazardous wastes are RCRA regulated hazardous wastes and that generators of these hazardous waste are subject to generator standards. However, DTSC also believes codification in part 262 does not preclude EPA from tailoring standards to certain groups of generator entities. Lastly, it appears EPA may have missed opportunities to set standards for pharmaceuticals and related hazardous wastes, such as emptied syringes, for other sectors that handle like hazardous wastes.

II. Specific Comments

Note: In general DTSC supports that the more stringent standards in proposed 266.502 be adopted for Primary Generators sending hazardous waste pharmaceuticals to Secondary Generators who will complete the hazardous waste determinations for the pharmaceutical hazardous wastes. However, for simplification and greater clarity

for all pharmaceutical hazardous waste generators, DTSC suggest the standards in 266.502 and 266.503 be combined into one set of standards

1. **Dietary Supplements**

DTSC is not aware of any dietary supplements that are RCRA hazardous wastes when discarded. Absent any specific factual examples, DTSC opposes the amendments to include them at this time. However, DTSC suggests EPA may consider adopting a petition procedure to include dietary supplements and other like-materials on a case-by-case basis.

2. **Credit and Creditable Waste**

DTSC believes the credit is not well enough understood by regulators to serve as an informed basis for a regulatory schema, for regulatory definitions, nor for regulatory enforcement activities. If EPA adopts a schema based on all or in part upon a *potential for credit*, what is to stop manufacturers from charging retailers \$0.02 extra and then returning \$0.01 as a credit on every item? In that event, all items would become potentially creditable. As EPA discusses, there is very little actual reuse and/or resource recovery occurring in the waste pharmaceutical arena. Therefore, it seems to DTSC, that EPA has made the correct choice in deciding that hazardous waste pharmaceuticals moving forward for evaluation are hazardous wastes (credit or no credit). Yet, incongruously, EPA has exempted hazardous waste pharmaceuticals destined for reverse distributors exempt from its proposed standards in part 266 subpart P. [See proposed 40 CFR 266.501(d)((1)(ii)]. DTSC recommends EPA not build a regulatory schema around this less than fully understood credit concept.

Primary Generators may not have the knowledge to readily complete the hazardous waste determination for the waste pharmaceuticals. The Secondary Generators (a.k.a. reverse distributors, a false term) may be able to do a better job of this hazardous waste management step. EPA can adopt a regulatory schema that allows Primary Generators to presume (all) the pharmaceutical wastes are hazardous wastes and allow them to send them under tailored hazardous waste management standards to the Secondary Generators, who, in turn, complete the hazardous waste determinations. These Secondary Generators can also be allowed to operate under their own set of tailored hazardous waste management standards. If these entities also make a credit determination at the same time, that falls outside the scope of the RCRA regulations.

3. **Proposed Definition of non-Creditable Hazardous Waste Pharmaceutical**

As mentioned above, the proposed definition appears to be a non-definition that is unnecessary and that is not really used in the proposed regulations. With this definition, it appears EPA is trying to define (or limit) which hazardous wastes are ineligible to be sent forward for evaluation by more knowledgeable Secondary Generators. DTSC recommends EPA simply set a clear regulatory standard, such as: "1) un-opened, 2) in original packaging, and 3) largely intact packaging" that can entirely eliminate this confusing issue. According to EPA's preamble, the

healthcare generators do not know which wastes are credit worthy and which are not. If that is indeed fact, then how can EPA expect generators and inspectors to comply with such a standard or definition? DTSC believes that generators and inspectors alike, could not function under this proposed standard. It is therefore recommended that this definition (and this concept) be removed from the final rule. ~~In the~~ Alternatively, EPA could adopt a clear listing of those items which EPA believes are non-creditable hazardous waste pharmaceuticals, including presumably all used, adulterated, and/or damaged hazardous waste pharmaceuticals.

At a minimum, the rule would be much more enforceable if EPA re-defined non-creditable HWP as: "any pharmaceutical waste not meeting the criteria in the definition of potentially creditable HWP." Although this is circular in nature, at least the definition would then specify some enforceable standard other than a generator's (perhaps wishful) expectation. In the final analysis, the only parts of these definitions that have real/actionable meaning are the following:

- unused,
- unexpired,
- expired for less than one year, and/or
- in sound packaging with original labeling capable of identification for hazardous waste purposes.

Any exclusion, exemption, tailored, and/or relaxed standards EPA wishes to devise for hazardous waste pharmaceuticals, including those eligible for and/or being sent for evaluation, can be clearly drafted and stated using those terms alone without reference to or creating a more elaborate economic euphemism or tautology.

4. Proposed Definitions of Evaluated and Potentially Creditable Hazardous Waste Pharmaceuticals

As mentioned above, DTSC does not know enough about this so called evaluation for credit or this credit to understand EPA's definitions or proposal. However, DTSC does believe a Secondary Generator can possibly simultaneously make this "business-credit determination" outside the scope of RCRA while also completing the RCRA step of making a hazardous waste determination for the Primary Generator. In light of this fact, DTSC recommends that EPA eliminate the creditable and non-creditable terms and concepts from the regulations and, instead define the process in terms of the "evaluation" and clarify that EPA is allowing the Secondary Generator to make the hazardous waste determination on behalf of the former generators. DTSC believes the rules can be practicable and enforceable as long as eligible pharmaceutical wastes moving forward for evaluation can be tracked and timed and distinguished from those which that have been evaluated. DTSC agrees with allowing a short timeframe, such as the proposed 21 days, to allow the hazardous waste determination to be completed. Regardless of the exact words codified by EPA in the final rule, the primary distinction in DTSC's opinion is that those wastes yet to be evaluated have incomplete hazardous waste determinations, whereas those that have been

evaluated are hazardous wastes with known RCRA listings, characteristics, waste codes and understood LDR requirements.

Therefore, DTSC proposes the following definition for Evaluated Hazardous Waste Pharmaceutical: A hazardous waste pharmaceutical received from a Primary Generator (of hazardous waste pharmaceuticals) that has been evaluated by the Secondary Generator (within 30 days of receipt – optional text), and that will not be sent to another Secondary Generator for further evaluation (i.e. for further hazardous waste identification).

5. **Proposed Definition of non-Pharmaceutical Hazardous Waste**

DTSC believes this definition is unnecessary if EPA adopts the schema suggested above. If so, the applicability sections in Part 262 can easily clarify that hazardous waste pharmaceuticals are subject to the two (new) sections for pharmaceutical waste generators and that all other hazardous wastes remain subject to the traditional generator standards (for VSQGs, SQG, and LQGs) without this definition.

6. **Proposed Definition of Pharmaceutical Reverse Distributor**

DTSC believes the discussion in section 11. of pp. 58025 of the preamble illustrates that this term is not related to RCRA hazardous waste management activities. As already noted, it also appears to be a falsehood that materials are actually returning up the supply chain in any significant quantities. As such, DTSC opposes the adoption of this term. DTSC recommends that EPA better identify, clarify, and then define the hazardous waste handling or management role this entity plays in the system if it does adopt this term into regulation. Please see the general comments above.

7. **Intersection of Controlled Substance and Hazardous Waste Pharmaceutical**

California's regulations have, for years, contained a limited, conditional exclusion for controlled substances that are incinerated. As noted above, DTSC believes this sort of exclusion in 40 CFR 261.4, provided the conditions are adequate, and is the best way to address the interface of these two controlling statutes. EPA might also consider excluding just the four known controlled substances if it wishes to be very narrow in the scope of such an exclusion. As noted in other areas, there are likely other parties (outside healthcare) that may benefit from such rules. For example, what if a person delivers such controlled substances to a Sheriff's Office for lack of any better alternative? The Sheriff may not fall within the scope of the current proposal or subpart 266. Re-locating the proposed rules as more generic exclusions in 261.4 (and 261.7 for syringes) appears to be a more versatile structure than the EPA proposal.

8. **Proposed Definitions of Long Term Care Facilities (LTCFs) and CESQG**

Based upon the preamble, most LTCFs are CESQGs. As such they would not be subject to the proposed rules. DTSC recommends that EPA consider amending 40 CFR 261.5 to exclude pharmaceutical hazardous wastes from the exemption

categorically and instead subject those generators to the (new) rules suggested (see above, Standards for Primary Generators of Pharmaceuticals) for their pharmaceutical hazardous wastes. Of course, these generators would still be VSQGs (CESQGs) for their ordinary hazardous wastes. Given EPA's explanations of the need for these rules and for its many more stringent aspects, this approach appears to be the most uniform solution to the LTCF situation. I.e., rather than amend 40 CFR 261.5 to require sending their wastes to a part 266 regulated entity, DTSC recommends EPA subject these entities to part 266 (as a Primary Generator) for their pharmaceutical wastes.

9. **Notification Using 8700-12 for Generator (Primary and Secondary)**

DTSC supports requiring notifications by generators, including health care facilities and others managing hazardous waste pharmaceuticals subject to the new rules. As mentioned above, including subjecting CESQGs (VSQGs) to these standards and requiring notifications from these entities as well. Without such notification, the anti-Sewering rule will likely not be enforced.

10. **Training Requirements for Generators**

Consistent with DTSC's above comments, DTSC recommends EPA apply the lower (SQG) training requirements to all Primary Generators and the higher (LQG) training standards to all Secondary Generators who complete the hazardous waste determinations, and who apply EPA hazardous waste numbers and make decisions about LDR applicability.

11. **Hazardous Waste Determinations**

DTSC supports not requiring Primary Generators to assign waste numbers and determine LDR standards as long as it is a condition of the set of alternate generator standards for pharmaceutical hazardous wastes which requires those wastes be sent to a Secondary Generator who becomes responsible for those determinations. As with the co-generator policy, EPA could suggest or require a contractual agreement between the two parties as part of its final rule.

12. **Accumulation Areas**

DTSC supports the use of working areas for accumulation containers and supports the divergence from CAAs and SAAs. However, DTSC recommends that facilities be required to maintain a list and map of all containers/locations (so that no containers/ locations are forgotten) if the number of locations/containers exceeds nine.

13. **Container Standards**

DTSC supports relaxed container standards, but would prefer to see that cloth and plastic sacks or bags not be allowable, unless they are used as part of a packaging system that has a rigid component as part of the container.

14. **Labeling for Primary Generators**

DTSC supports the labeling of containers as “Hazardous Waste Pharmaceuticals” and not requiring hazardous waste numbers for containers moving forward for evaluation. DTSC recommends that EPA-specified, color coded, date shipped labels be required as discussed above. This will facilitate the identification of “yet-to-be-evaluated” containers by receiving facilities and by inspectors in the field.

15. **Accumulation Time Limit**

DTSC supports the longer accumulation time limit to allow transportation efficiencies. However, DTSC recommend that the limit be amended to include “up to one year or 6000kg, whichever occurs first.” DTSC suggests EPA may find some other quantity equates to what is a cost effective quantity.

16. **LDRs**

DTSC supports not requiring Primary Generators to complete LDR evaluations (how could they without EPA waste codes?) as long as it is a condition of the set of alternate generator standards for pharmaceutical hazardous wastes which requires those wastes be sent to a Secondary Generator who becomes responsible for those determinations on behalf of the Primary Generators.

17. **Manifesting**

DTSC recommends manifests be used to track hazardous waste pharmaceuticals from Primary Generators to Secondary Generators without waste code, by EPA creating a single unique code. Primary Generators would use a single unique code when making such shipments to Secondary Generators who will complete the hazardous waste determinations on behalf of the primary generators. EPA should also clarify that Secondary Generators are allowed to accept these manifested hazardous waste shipments. (The preamble suggests it is not allowable under current regulations for a non-permitted TSDF, yet no citation was provided and no clear prohibition can be found in the regulations, in DTSC’s opinion. A simple regulation stating: “notwithstanding section 26x.xx, Secondary Generators may receive ...” would be very helpful for all.)

18. **Records Retention**

DTSC supports keeping records for three years. In this comment document, this would apply to manifests and exception reports. Primary Generators who send their hazardous waste pharmaceuticals to Secondary Generators who complete the hazardous waste determinations would not have to keep records of their decision to follow the hazardous presumption. Instead, the Secondary Generators would maintain the records for the final hazardous waste determinations on behalf of the Primary Generator.

19. **Releases**

DTSC supports the 266.502(k) proposal.

20. LTCF Self-generated Hazardous Wastes

DTSC is neutral on the requirement to inventory and collect the self-generated (household) hazardous waste pharmaceuticals from residents. The wording could be included to clarify that if a LTCF does accept these hazardous wastes from its residents, then it must manage them per these rules. This is necessary because EPA says HHW remains its exclusion/status into the future.

21. CESQG Wastes Acceptance by LTCFS

Please see comment 8 above. DTSC recommends CESQGs be subject to the proposed standards themselves.

Note: the following specific comments build upon the above comments by further clarifying certain aspects for the Secondary Generators as DTSC has proposed they be called (i.e., the evaluators). For the most part, the waste handling standards for safe handling should be essentially same. Certain clarification are made herein, where circumstances at the second locations may be slightly different.

22. Potentially Creditable Pharmaceuticals as Products

DTSC agrees with and supports EPA's recent findings that these pharmaceutical wastes are hazardous wastes and are not products. ~~DTSC agrees believes that the~~ Evidence placed before DTSC and regulatory agencies ~~supports~~ shows that the pharmaceuticals are not being reclaimed, nor reused in any significant quantities. DTSC supports EPA's rescission [revocation] of its previous guidance documents in the final rule. In line with EPA's findings, DTSC strongly recommends, as previously mentioned above, a line item amendment to 40 CFR 261.2 clarifying that pharmaceuticals, as defined in 260.10 are wastes when sent to Secondary Generators for completion of the hazardous waste determination by trained, skilled and more knowledgeable persons. If ultimately EPA retains the "potentially creditable" moniker, DTSC strongly suggests that EPA add that moniker to the line item discussed above.

Under EPA's current proposal when one steps through the regulations, starting on page 58083, as proposed (without reading and using any preamble discussion), the the following will/may occur:

A healthcare generator, who is uneducated in hazardous waste rules, will deem all pharmaceutical material potentially creditable because this person does not know otherwise, and would like to receive credit. In part 261 there is no reason to believe these items are wastes; the generator does not know anything about disposal, reuse, or reclamation. It may be worthy of credit instead of regarded as a waste. Then, in part 262, the generator reads nothing to indicate potentially creditable items are not products, but instead are hazardous wastes. If the generator does turn to part 266, the generator will see nothing in the definition section that would indicate the "potentially creditable materials" are hazardous wastes, but will be left with the final definition of potentially creditable *hazardous*

wastes. Despite that phrase, the generator will see that it is not regulated via 266.501(d)(1)(ii), supporting that the material are unregulated. In light of the above impact, DTSC asks EPA to consider it alternative approach designating two kinds of regulated generators for hazardous waste pharmaceuticals.

23. Hazardous Waste Determinations for Evaluators (Secondary Generators)

DTSC recommends that the standards for secondary generators require completion and documentation of the hazardous waste determinations for the waste pharmaceuticals these entities receive under a presumption of being hazardous. DTSC suggests the final regulations could require a contractual agreement that specifies that these entities will complete this action and will return documentation of such completion to the Primary Generators. DTSC supports a relatively short timeframe, 21 days, as proposed by EPA, for such completion and a labeling or marking requirement as discussed above, upon completion.

24. Accumulation Time Limit & Labeling

DTSC would apply the same standard as in comment 11 above. However, DTSC expects the secondary generators would reach the proposed quantity limit of 6,000 kg (or another value set by EPA) much sooner. Still, the standard for safe handling should not differ in DTSC's mind; the wastes have not changed chemically or physically during the transfer from one location to the other. Containers should be labeled Hazardous Waste Pharmaceuticals. Once evaluated, hazardous waste labels should be affixed within three days.

25. Sewer Disposal Prohibition

DTS supports this prohibition applying to all entities managing hazardous waste pharmaceuticals, including VSQGs (CESQGs) SQGs, LQGs, TSDFs, and of course Primary and Secondary Generators as described herein. For SQGs and LQGs, this prohibition need only be codified in those sections of Part 262 if EPA decides to allow generators the option of following the traditional hazardous waste rules or the new rules for pharmaceuticals. If the rules for hazardous waste pharmaceuticals are not optional under the applicability section of part 262, then this prohibition need not appear in the SQG and LQG sections (currently proposed 262.16 and 262.17). To re-iterate, DTSC believes EPA should utilize its CWA authority to exclude hazardous waste pharmaceuticals from the 40 CFR part 261.5 exemption and should also simultaneously codify the sewerage prohibition in that section. EPA could also use its solid waste (Subtitle D) authorities, perhaps.

26. DEA and Empty Container Exclusions

See above. No additional comments.

27. **Sending Evaluated Hazardous Waste Pharmaceuticals to TSDFs**
DTSC believes the Secondary Generators should be subject to the same pre-transport standards and transportation standards as are LQGs (i.e., in proposed 262.17). To reiterate, DTSC supports shipping hazardous waste pharmaceuticals to Secondary Generators under manifests as well with a new single waste code promulgated by EPA for his purpose (presumed hazardous pharmaceuticals shipped for evaluation, EPA hazardous Waste # XYZ1).
28. **Imports and Exports**
DTSC supports EPA's proposal to apply the existing hazardous waste rules for Imports and Exports of hazardous waste pharmaceuticals, for both Primary and Secondary Generators, as discussed herein.
29. **Notification for Secondary Generators**
DTSC supports EPA amending the 8700-12 form and requiring notifications of activities for all Secondary Generators who accept hazardous waste pharmaceuticals under manifest and complete the hazardous waste determinations on behalf of the Primary Generators of pharmaceutical hazardous wastes.
30. **Inventories for Secondary Generators**
DTSC supports EPA's proposal to require inventories and to make copies available to inspectors, as well as applicable portions available to Primary Generators they contract with.
31. **Security**
DTSC supports EPA's proposal, in proposed 266.510(a)(3), for security for Secondary Generators of hazardous waste pharmaceuticals.
32. **Accumulation Time Limit**
Please, see comment 24 above.
33. **Contingency Plan, and Closure**
DTSC supports applying the newly proposed, and to hopefully be revised, Contingency Plan and Closure requirements for LQGs to Secondary Generators.
34. **Reporting and Recordkeeping**
DTSC supports un-manifested waste reports and all recordkeeping proposed by EPA. DTSC also recommends maintaining for three years: copies of all completed hazardous waste determinations made on behalf of Primary Generators and copies of all submitted 8700-12 forms regarding pharmaceutical hazardous waste handling.
35. **Sending Hazardous Waste to another Secondary Generator**
DTSC recommends that the standards for a Secondary Generator clearly state that a Secondary Generator that sends hazardous waste pharmaceuticals to another Secondary Generator for Evaluation becomes the Primary Generator and is

subject the "Standards for Primary Generators of Pharmaceuticals," as proposed in these comments, just as a TSDF may be subject to part 262 under the present regulations.

36. Additional standards for Secondary Generators

DTSC supports EPA's application and adoption of all of the additional standards in proposed 266.510(c) and (d) to Secondary Generators of hazardous waste pharmaceuticals as DTSC has described that entity herein.

37. Part 268 Standards

DTSC supports EPA's proposal to amend the LDR standards accordingly to the proposed rules.

38. Part 273 Prohibition

DTSC supports EPA's proposal to regulate health care industry generators as well as other industrial generators of hazardous waste pharmaceuticals under tailored generator standards and not under the universal waste rules. However, DTSC questions the extent of the prohibition as proposed. DTSC suggests that EPA revise the proposed 66273.80(d) prohibition to allow for States to adopt universal waste rules including household hazardous wastes and possibly CESQG hazardous wastes into their universal waste rules as this rule may facilitate collection programs that have objectives that are directly in synch with the stated goals of EPA's proposed rule. DTSC understands that EPA views its RCRA rules with the 261.4(b)(1) exclusion in mind. However, DTSC would like to point out to EPA that not all states implement this type of exclusion, nor does the 40 CFR 273.8(b)(1) provision operate consistently with this RCRA exclusion. In addition, EPA's creation of the universal waste rule has spurred the creation of states UWRs. The prohibition as drafted could have impacts that potentially negatively impact states efforts to collect hazardous waste pharmaceuticals, both RCRA and non-RCRA.



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

NOV 4 2011

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Containers that Once Held P-listed Pharmaceuticals

FROM: Suzanne Rudzinski, Director *Suzanne Rudzinski*
Office of 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 $\leq 0.3\%$, 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:

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

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