

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
5 Post Office Square, Suite 100
Boston, MA 02109-3912

July 22, 2011

David Gamblin, PharmD
Director of Pharmacy
Holyoke Medical Center
Holyoke, MA 01040

Re: Hazardous wastes status of used and unused pharmaceuticals (i.e., nicotine gum/patches and wrappers; and warfarin wrappers)

Dear Mr. Gamblin:

Thank you for your recent inquiries (dated April 6 and May 3, 2011) regarding the hazardous waste status of certain pharmaceutical products and packaging, specifically, used and unused nicotine gum and patches, the wrappers from the nicotine gum and patches, as well as the wrappers from warfarin tablets. The purpose of this letter is to address your questions and provide additional guidance regarding the handling of these types of items.

For your information, we have attached a regulatory interpretation letter issued by EPA's Washington D.C. (Headquarters) office dated August 23, 2010 which specifically addresses the regulatory status of nicotine gum and dermal patches. In addition, included in your inquiries was a July 17, 1998 letter from the MassDEP in which the term "manufactured articles" is used to describe certain unused nicotine products being discarded. Please note that EPA's August 23, 2010 letter also addresses this term and previous conflicting interpretations for dermal patches and concludes that this term would not apply to unused nicotine gum or patches when being discarded. In particular, the letter provides an explanation of why these products are more appropriately classified as listed hazardous wastes.

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, both nicotine and warfarin at concentrations greater than 0.3%, are P-listed wastes (acutely hazardous wastes) when discarded, and carry the waste codes P075 and P001, respectively. (Note warfarin at concentrations of 0.3% or less is not considered acutely hazardous wastes and carries the waste code U248). Please be aware that it is ultimately the responsibility of each generator to determine whether a particular waste they generate is either a listed or characteristic hazardous waste.

The following provides EPA Region I's position in response to your specific concerns:

Used Nicotine Gum and Dermal Patches. As noted in EPA's August 23, 2010 letter, once the gum or patch is used (i.e., the nicotine administered), it would be considered as having been used for its intended purpose and no longer considered a commercial chemical product and, therefore, not a P-listed hazardous waste when discarded. However, the waste should be evaluated for hazardous characteristics to determine if it exhibits any of the hazardous waste characteristics.

Unused Nicotine Gum and Dermal Patches. Since these items are commercial chemical product (CCP) formulations of which nicotine is the sole active ingredient and are discarded prior to being administered or "used" (e.g., the product has exceeded its expiration date or has become unusable due to a compromise in product integrity), these "unused" products would be considered a P-listed (P075) hazardous waste when discarded. (See 40 CFR 261.22(d) "Comment." See also, EPA's August 23, 2010 letter.)

Pharmaceutical CCP Packaging

EPA Headquarters is currently evaluating the management of hazardous pharmaceutical wastes (which would include wrappers from nicotine patches/gum and warfarin) and may issue future guidance in this matter. Until such time that EPA HQ issues relevant guidance, we believe it is appropriate for you to follow guidance provided by the Massachusetts Department of Environmental Protection (MassDEP). Note language in MassDEP's July 26, 2010 email from Mathew Barber to James Paterson (as reflected in your email of May 24, 2011 to Janet Bowen, EPA) provides relevant guidance to answer your questions regarding the proper management of pharmaceutical packaging. (See excerpt below:)

"Any container or packaging that held a warfarin tablet that is about to be administered would not carry the RCRA listed waste codes since the tablet is removed as a product. The container can be managed as solid waste provided there is no visible residue on such wrappers/packaging. Containers include foil/blister packs and paper/plastic cups to administer individual doses. If the tablet is determined to be a waste while still in the container, the P- and U- waste codes may apply to both the tablet and the packaging."

Under section 3006 of RCRA, EPA Region 1 has authorized the Massachusetts hazardous waste program. This authorization allows the state program provisions to be in effect and enforceable by MassDEP, as well as EPA. Since the regulations applicable to hospitals are part of the Massachusetts authorized state program, we have consulted with the MassDEP on this matter.

Region I provides email notification of new EPA guidance relating to hospitals through Janet Bowen of EPA Region I's Office of Environmental Stewardship. If you are not currently on this list, you may wish to contact Ms. Bowen at 617-918-1795.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Sanderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mary Sanderson, Chief
Remediation and Restoration II Branch
Office of Site Remediation and Restoration

cc: James Paterson, MassDEP
Janet Bowen, EPA

Enclosure/Link to EPA's RCRA Online collection of regulatory interpretations

EPA Headquarters' August 23, 2010 letter addressing dermal patches and additional nicotine products (RCRA Online #14817):

[http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44ECDC852577ED00624E8F/\\$file/14817.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44ECDC852577ED00624E8F/$file/14817.pdf)