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June 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fischers Lane, Room 1061
Rockville, MD 20852

Docket Number 02N-0204 – Bar Code Label Requirement for Human Drug Products

The purpose of this letter is to comment on the Food and Drug Administration's (FDA's) proposed rule, Bar Code Label Requirement for Human Drug Products and Blood. This rule would require drug manufacturers to place bar codes containing the National Drug Code on prescription and many over-the-counter drugs. The proposed rule was made available for public comment on March 14, 2003 (68 FR 12500). Tri-TAC would like to request that the FDA include a requirement in this rule that bar code labels for human drugs include the waste disposal status of the drug under the federal Resource Conservation and Recovery Act (RCRA). Such a measure would reduce the improper disposal of pharmaceutical wastes that potentially threaten human health as well as the environment.

Background

Tri-TAC is a California-based organization comprised of members from public agencies and other professionals responsible for wastewater treatment. It is a technical advisory committee, consisting of representatives from the California Association of Sanitation Agencies, the California Water Environment Association, and the League of California Cities. The constituency base for Tri-TAC treats and reclaims more than 2 billion gallons of wastewater each day, and serves most of the sewered population of California.

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Pharmaceuticals in the Environment

Recent research has revealed that drugs are in the environment both as a result of improper disposal of RCRA-regulated drugs and the discharge of both metabolized and unmetabolized pharmaceuticals from patient excreta into the sanitary sewer. In a study conducted in 1999 by United States Geologic Service (USGS)[1], 139 streams in 30 states were analyzed for 95 different organic wastewater contaminants, including pharmaceuticals. The study found that pharmaceuticals were present more commonly in surface waters than had been previously expected. Four antibiotics were found in over 10% of samples analyzed (erthromycin, lincomycin, sulfamethoxazole, and trimethoprim). Codeine was found in 11% of samples and the antihypertensive diltiazem was found in over 13% of samples. Acetaminophen was found in 24% of samples and ibuprofen was found 10% of the time. Caffeine was found in 65% of samples. Steroids and hormones were also commonly found, with 17α-ethynyl estradiol (a hormone used in birth control pills) found in 16% of samples analyzed. Safe levels for many of these pharmaceuticals have not yet been established. While they may not cause acute toxicity in aquatic organisms, they may interfere with endocrine systems, particularly when exposure occurs during developmentally sensitive times such as before birth.

Mercury is commonly used in pharmaceuticals as a preservative, and all pharmaceuticals containing mercury designate as RCRA waste. Premier Safety Institute, a leading buying group for hospitals, published a list of 674 mercury-containing pharmaceuticals. Drugs with mercury include sulfacetamide solution (an eye solution), tetanus shots, contact lens cleaners, Preparation H, mumps skin tests, nasal sprays (Neo-synephrine, Dristan) and ophthalmic drops[2]. But because they are not labeled as such, many mercury-containing pharmaceutical wastes are improperly disposed in biohazard containers, trash, and sanitary sewers. This can ultimately contribute to a negative impact on our environment.

Pharmaceuticals as RCRA Waste

Pharmaceuticals regulated under RCRA (i.e., regulated as hazardous wastes) must be disposed of at a permitted hazardous waste facility. RCRA regulates hazardous wastes that are ignitable, reactive, toxic, or corrosive. Wastes containing hazardous levels of certain toxic chemicals and heavy metals (e.g., barium, mercury,

[1] "Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance," March 15, 2002 Environmental Science & Technology, v. 36, no. 6, pages 1202-1211.
[2] For the entire list see http://www.premierinc.com/all/safety/publications/10-2_downloads/02_HG_drug_list_08-22-02_public.xls.

and silver) are also regulated by RCRA. Some drugs contain active ingredients listed as hazardous discharged chemical products on the RCRA U and P lists.

Information about the RCRA status of most pharmaceuticals is not readily accessible. Pharmaceuticals do not come with Material Safety Data Sheets and their labels do not contain a list of hazardous ingredients. Because of this, many pharmaceutical wastes subject to RCRA are improperly disposed to the sanitary sewer, solid waste, and/or biohazard disposal systems[3]. Providing RCRA disposal information to pharmacists and medical facilities would eliminate a major barrier to compliance, as well as decrease negative impacts on the environment.

Recommendation

Tri-TAC recommends that the FDA require bar code labels on pharmaceuticals to include information on whether the drug is regulated under RCRA when it becomes a waste. The information could be included very simply, because it is a yes-or-no question as to whether a waste drug is regulated under RCRA. A single digit could be put at the beginning or end of the National Drug Code. The digit could have a value of zero if the drug is not regulated under RCRA when it becomes a waste, and a value of one if the drug is regulated under RCRA when it becomes a waste. To determine whether a waste drug is regulated under RCRA, medical personnel could simply look at the first (or last) digit on the bar code. Manufacturers, who are responsible for including the bar code, should be fully aware of whether their product is classified as a RCRA waste when it is disposed. Therefore, addition of the RCRA classification in the bar code will not be a burdensome obligation for manufacturers.

Contact Information

Thank you for your consideration of our comments. If you have any questions about this letter or would like additional information, please contact me by phone at (510) 287-1496 or by e-mail at dwilliam@ebmud.com.

Sincerely,

David R. Williams

David R. Williams
Chair, Tri-TAC

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[3] Pharmaceutical Waste Survey, Local Hazardous Waste Management Program in King County, Interagency Regulatory Analysis Committee, Pharmaceutical Workgroup, April 15, 2003, SQG-RR-6(11/02). Available at http://www.metrokc.gov/hazwaste/lhwmp/Pharm_IRAC_WasteSurveyReport.pdf.

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