3105.9809

STATE OF CONNECTICUT
DEPARTMENT OF ENVIRONMENTAL PROTECTION

September 14, 1998

Ms. Linda Baetz
Program Manager, Hazardous and Medical Waste
~~Department of the Army~~
US Army Center For Health Promotion and Preventive Medicine
5158 Blackhawk Road
Aberdeen Proving Ground, Maryland 21010-5422

SITE NAME: _____
TOWN: _____
FILE TYPE: _____

RE: Returned Pharmaceutical Products

Dear: Ms. Baetz

The Connecticut Department of Environmental Protection ("DEP"), Bureau of Waste Management, acknowledges receipt of your June 29, 1998 letter, including the reference documents you attached. This Bureau has reviewed your proposal for managing unused pharmaceutical products that are to be returned by Army medical centers to wholesalers, retailers, and/or third party service companies for ultimate disposition.

The DEP encourages facilities that dispense pharmaceutical products to develop best management practices that will minimize the amount of unused pharmaceutical materials that require management as waste and appreciate your efforts with respect to this issue. However, based on the information provided, staff can not concur with your management proposal. The Bureau would like to provide the following points of clarification on our position.

Your proposal appears to be based on the assumption that all returned pharmaceuticals have the potential for reuse. DEP does not share this assumption. Your June 29, 1998 request provides references to the reuse potential of returned pharmaceutical products but the documentation does not provide enough information to support this claim. The letter from Merck Sharp and Dome dated March 26, 1981, included with your request, indicates that most pharmaceutical items returned to them are not recovered, but disposed of. As EPA pointed out in their 1991 memo, pharmaceutical products being returned with no intention of being legitimately reused would be classified as solid waste and potentially a hazardous waste (i.e., cytotoxic pharmaceuticals).

In addition, you also indicate that the dispenser of such pharmaceutical products (i.e., Army medical centers) generally does not know if returned items will be reused, reclaimed, sold, destroyed, or disposed of. Therefore, it is unclear as to how such a dispenser can demonstrate, with the adequate documentation, that the materials they are returning through a third party vendor have legitimate reuse potential. Clearly, expired pharmaceuticals returned to third party vendors would have to be documented that there is a reasonable expectation that these materials will be reused in some manner after being returned. All parties involved in the management of returned pharmaceutical items, including persons returning such item(s), are responsible to ensure that materials to be returned have the potential for legitimate reuse and must keep adequate documentation that supports this claim.

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The DEP supports programs for pharmaceutical products being returned for reuse provided the program is used as a means to facilitate the legitimate reuse of the pharmaceutical products, rather than as a means of disposal. However, such a program should at a minimum, identify: 1) the markets for products to be returned for reuse, including expired shelf life products; 2) documentation that indicates the materials are being reused; and 3) the means by which these pharmaceuticals are being legitimately reused (i.e., repackaged or redistributed). In addition, the proposal should, at a minimum, include: 1) a description as to how the product dispensers are informed as to which products are potentially reusable and/or the standard(s) that would be utilized to make this determination; 2) a list of vendors that provide the means to reuse such items; and 3) a description of the documentation that shall be maintained to support such a program.

The Department reserves judgement on the legal conclusions contained in your letter and retains the ability to modify the Department's regulatory interpretation on this matter in the future.

I hope this response adequately addresses your request and proves useful. Should you have any comments or questions regarding this issue, please feel free to contact Paul Franson of my staff at (860) 424-3565.

Sincerely,

Richard J. Barlow

Richard J. Barlow
Chief
Waste Management Bureau

RJB/pif

DEPARTMENT OF THE ARMY
U.S. ARMY CENTER FOR HEALTH PROMOTION AND PREVENTIVE MEDICINE
5158 BLACKHAWK ROAD
ABERDEEN PROVING GROUND, MARYLAND 21010-5422

REPLY TO ATTENTION OF

June 29, 1998

Hazardous and Medical Waste Program

Bureau of Waste Management
Department of Environmental Protection
79 Elm Street
Hartford, Connecticut 06106-5127

Dear Sirs:

BACKGROUND: Army medical centers, hospitals, and clinics throughout the country stock various pharmaceuticals that are dispensed to patients. Some of these items (after they become a waste) have the potential to be regulated under the Resource Conservation and Recovery Act-Subtitle C (RCRA-C) when they meet the criteria for listed/characteristic hazardous wastes as described in Subparts C and D of 40 CFR 261 (see attached list).

CURRENT SITUATION: Many pharmaceutical companies provide credit back to the user for returned pharmaceuticals. The majority of these items are classified as solid wastes, but some could be regulated as hazardous wastes under certain circumstances. The Army has stressed that the return of pharmaceutical items, which have the potential to be a hazardous waste, to either the manufacturer or a third party service company should occur **before** the expiration of a product. If the product has expired and if it should be regulated as a hazardous waste, the Army advises that it not be returned using a third party. If expired, the hazardous waste is currently handled through installation hazardous waste disposal contracts. We would like for Army medical facilities to be able to return **all** expired pharmaceuticals to a third party service company.

PROPOSAL: We propose that waste pharmaceutical products (those which may be regulated as a hazardous waste), to include cytotoxics, which are returned by Army medical centers to a third party service company not be classified as a hazardous waste until the products have reached their final destination. That would imply that the third party service company may give credit for the item and then would determine the RCRA-C classification if the item required disposal action. The third party service company would, in effect, be the generator of record for the waste. Pharmaceuticals are returned for many reasons to include: oversupply, recall, and expiration of the product. A dispenser of such products generally does not know if the returned item will be reused, reclaimed, sold, destroyed, or disposed of.

We have attached documents of correspondence between the U.S. Environmental Protection Agency (EPA) and other agencies, those enclosures are as follows: (1) Letter by Merck Sharp & Dohme dated April 1, 1981, requesting review of their current HW disposal procedures for pharmaceutical products; (2) Letter by the EPA, Washington, D.C. dated May 13, 1981, agreeing with the company's disposal procedure; (3) Letter by the EPA, Washington, D.C., dated May 16, 1991, stating a pharmaceutical is not a solid waste until the manufacturer or wholesaler makes that determination; (4) Letter by the Department of Environmental Protection, Louisville, Kentucky, dated December 10, 1996, stating nitroglycerine medicine is not a hazardous waste; and (5) A listing of RCRA hazardous drugs in question.

We seek your State's regulatory interpretation regarding the RCRA classification of returned, expired pharmaceuticals. We urgently ask for your input because we are developing policy guidance to our military health care facilities and wish to comply with State requirements. A response from you is requested as soon as possible. We hope to implement this policy by October 1, 1998. If you have any questions please contact me at (410) 671-5234 or Dominique Aulgur at (410) 612-7958. After July 12, 1998, our telephone numbers will be (410) 436-5234 or (410) 436-7958, respectively.

Sincerely,

Linda L. Baetz
Program Manager
Hazardous and Medical Waste

Enclosures

KIM MIKO
ENVIRONMENTAL SPECIALIST
ENVIRONMENTAL BRANCH
ENERGY, ENVIRONMENTAL, & NATURAL RESOURCES DIVISION
DIRECTORATE OF PUBLIC WORKS (ATZT-DPW-EE)
BUILDING 2101 – SECOND STREET & REPLACEMENT
FORT LEONARD WOOD, MO 65473-5000

PHONE (573) 596-0131 -THEN- Ext. 6-8635

FAX (573) 596-0869 USERS -- CIRCLE NUMBER FOR RECEIVERS TO USE

SEND TO	From
USCHPPM	KIM MIKO
Attention -- Individual: Jennifer Pedley	Date: 13 NOV 97
Fax Number: (410) 671-5237	Phone Number: (573) 596-0131, Ext. 6-8635

☐ Urgent ☐ Reply ASAP ☐ Please Comment ☐ Please Review ☐ For your Information

Total pages, including cover sheet:

COMMENTS

Am faxing you info from EPA concerning the letters of pharmaceuticals to the manufacturers. Please compare this to the McNamm contract that I sent to you earlier and provide your interpretation

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MSD
MERCK SHARP & DOHME

RECEIVED
APR - 1 1981

DIVISION OF MERCK & CO., INC., WEST POINT, PENNSYLVANIA 19486

March 26, 1981

Mr. Alan Corson,
Chief-Waste Characteristics Branch
Hazardous Waste Management Division (AW-465)
Office of Solid Waste
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Corson:

I recently had the opportunity to meet with Ms. Claire Welty from your office, at our plant on March 6, 1981. During her visit, I briefly summarized a matter concerning hazardous waste management that has been of concern to our Company. Ms. Welty recommended that we submit this matter in writing to your office for consideration.

Merck Sharp & Dohme, Division of Merck & Co., Inc., is located in West Point, Pennsylvania where we manufacture ethical pharmaceutical and biological products. Finished goods are shipped to sixteen branch operation facilities located throughout the country. The finished goods are then distributed to customers from the branch operation facilities. A small percentage of the finished goods are returned to the branch operation facilities on a regular basis. Usually returns occur when a pharmacist has kept a product beyond the expiration date. Occasionally, a pharmacist may return a product for some other reason, such as lack of sales. Also, a product may be returned if we initiate a recall for any one of numerous reasons. These return goods are shipped from all sixteen branches to our West Point plant.

Most return goods shipped to West Point are discarded either for business reasons or because Food and Drug Administration regulations prevent us from recovering them. Once they reach the plant, return goods are disposed, but only after they have been checked at our plant under the supervision of our Security Department. They are either incinerated or transferred to a solid waste crusher for destruction prior to being landfilled. In this manner, we can account for and control the disposal of all return goods in a uniform manner at a central location. The centralized control of our return goods has been practiced effectively for over 30 years. It is essential to our standards of practice to assure uniformity in handling products, even when discarded.

After careful review of the Part 261 regulations, Identification and Listing of Hazardous Waste, we have determined that some of our return goods should be

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U.S. Environmental Protection Agency

March 26, 1981

interpretation is correct that insofar as returned goods are concerned, our branch operation facilities are not subject to the hazardous waste generator standards of the regulations. Thank you for your cooperation in this matter.

Very truly yours,

Steven C. Wittmer

Steven C. Wittmer,
Environmental Facilities Engineer,
Facilities Engineering

SCW:cg

OEIG

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

FILE COPY

MAY 16 1991

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

Mark J. Schulz
President
Pharmaceutical Services, Inc.
Browning-Ferris Industries
757 N. Eldridge
Houston, Texas 77079

Dear Mr. Schulz:

This responds to your February 22, 1991 letter to David Bussard requesting a determination regarding the regulatory status of pharmaceutical products that are returned by the dispensers of these products to the manufacturers, wholesalers, or to a third-party service company that will facilitate the processing, crediting, and, if needed, appropriate disposal of the returned products. Currently, such products are returned directly to the manufacturer or wholesaler, who credits the dispenser for the products and determines whether the products are to be reused, reclaimed, or appropriately disposed. BFI Pharmaceutical Services, Inc. (BFI-Pharm) intends to provide this reverse distribution service to the pharmaceutical industry.

As I understand your letter, pharmaceutical products may be returned for many reasons, including, among others: 1) an oversupply at the dispenser, 2) expiration of the recommended shelf life, 3) a recall has been initiated by the manufacturer, 4) the product was received as a result of a shipping error, and 5) the product has been damaged. You state that, in general, the dispensers of the pharmaceutical products do not know whether the returned products will be reused, reclaimed, sold overseas, or disposed (i.e., they are not able to determine whether these materials are solid wastes). Because the dispensers receive credit for the returned products (either because the products actually have real value to manufacturer or because such credits are part of a competitive marketing approach), the products have a monetary value to the dispensers and they would not normally assume such materials to be wastes.

Under our current regulations, such returned products are not considered solid wastes until a determination is made to discard these materials. The returned products themselves (being "commercial chemical products" under our classification system) are considered [illegible] (assuming that this determination is beyond the ability of the dispenser), then those products managed within the reverse distribution system are not solid wastes until the manufacturer or wholesaler makes the determination to dispose of them. This view is based on our understanding that the system is established as a means to facilitate the recycling of reusable pharmaceutical products, rather than a

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waste management system. We will be interested to learn if your data, which will be computerized, will support this assumption. At the current time there does not appear to be any reason for EPA to change its policy regarding this type of reverse distribution system simply because a third-party service company is involved rather than the manufacturers themselves.

I would like briefly to bring to your attention two issues that bear generally upon reverse distribution systems, although neither appear to be of concern in the BFI-Pharm situation. First, EPA does not intend for hazardous waste brokers to use a reverse distribution system to relieve generators of the responsibility for making determinations about the discarding of materials as wastes. It remains the generator's responsibility to properly identify secondary materials. Second, a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place. Of course, as I discussed above with respect to the BFI-Pharm situation, to the extent that the materials involved are unused commercial products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.

This interpretation is based on the current set of Federal RCRA regulations. However, as you know, authorized States may regulate or interpret the regulations differently, and State requirements are the applicable standards in authorized States. You should contact the appropriate State regulatory agencies for a more definitive regulatory determination for their respective jurisdictions.

I hope this has sufficiently answered your questions. Should you have any further questions regarding EPA's policies, you may contact David Bussard at (202) 382-4637.

Sincerely,

Sylvia K. Lowrance
Director
Office of Solid Waste

JAMES E. BICKFORD
Secretary

PAUL E. PATTON
Governor

COMMONWEALTH OF KENTUCKY
NATURAL RESOURCES AND ENVIRONMENTAL PROTECTION CABINET
DEPARTMENT FOR ENVIRONMENTAL PROTECTION
LOUISVILLE REGIONAL OFFICE
Division of Waste Management
312 Whittington Parkway, Suite 201
Louisville, Kentucky 40222

December 10, 1996

Ms. Kay Bennett
USAARMC & Ft. Knox
Directorate of Engineering & Housing
Maxwell Street
Ft. Knox, Kentucky 40121-5000

Dear Ms. Bennett:

As we discussed on December 2, the nitroglycerine medicine from Ireland Hospital, whose shelf life has expired can be returned to the manufacturer for credit and would not be regulated as a hazardous waste under the Kentucky hazardous waste program.

Also, in a December 3rd phone conversation regarding the satellite accumulation area in Building 1022 with Joetta Cox, this area was so designated because the material was not declared a waste until it was inspected and placed in the building. The waste is labeled and placed in a locked, signed cabinet which is inside a locked room in Building 1022. The building would then be managed as a satellite accumulation area.

If you have any questions regarding these issues, please contact my office at (502) 595-4254.

Sincerely,

Mark Caines

Mark Caines
Envir. Inspector III
Louisville Regional Office

MCA:dm

The following is a list of RCRA-hazardous drugs and their EPA hazardous waste numbers. This list is not inclusive of all agents as there are new products being developed:

Product	EPA#
CYTOTOXICS	
Azaserine	U015
Chlorambucil (Leukeran)	U035
Cyclophosphamide (Cytoxan, CTX)	U058
Chlornaphazin	U026
Daunomycin (Daunorubicin)	U059
3,3'-Dichlorobenzidine	U073
Diethylstilbestrol (DES)	U089
3,3-Dimethoxybenzidine	U091
p-Dimethylaminoazobenzene	U093
Ethylene Thiourea	U116
Maleic Hydrazine (Maleic Hydrazide)	U148
Melphalan (Alkeran)	U150
4,4-Methylene Bis (2-chloroaniline)	U158
Mitomycin-C Mutamycin)	U010
1-Naphthalenamine	U167
Streptozocin (Zanosar, SZNO)	U206
O-tolidine	U328
Uracil Mustard	U237
OTHER	
Epinephrine	P042
Iodine Tincture	D001
Kit Antidote Treatment Cyanide	D001
Kit Insect Sting	P042
Nitroglycerin	P081
Physostigmine	P208
Physostigmine Salicylate	P188
Shampoo with Benzene Hexachloride	U129
Shampoo with Lindane	D013
Chlorambucil	U035
Warfarin Sodium	P001