

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF SOLID WASTE

MAY 13, 1981

OFFICE OF WATER
AND WASTE MANAGEMENT

Mr. Steven C. Wittmer
Environmental Facilities Engineer
MERCK SHARP & DOHME
West Point, Pennsylvania 19486

Dear Mr. Wittmer:

Your letter of March 26, 1981 requests our interpretation of the RCRA hazardous waste regulations as applied to products eventually discarded at your West Point plant.

40 CFR §261.33 is the controlling provision: the materials you describe, including U245, become hazardous wastes "if and when they are discarded or intended to be discarded...". [Emphasis added]. We underscore the word "when" because the event of discard, or the time of decision to discard, is determinative. Until a material referenced by section 261.33 is actually discarded, or the decision is made to discard the material, it is not subject to RCRA regulation.

As we understand, the decision by Merck Sharp & Dohme whether to discard a given product is not made until after the product has been returned to the West Point plant, following a check by your Security Department. Moreover, as we understand, your procedures for segregating returned goods for reclamation or disposal via either incineration or landfill take place only at the West Point plant. Given these facts, and assuming that your branch operations have no role in the decision to discard a particular material, we conclude, as to materials in the form of commercial chemical products on the P or U lists of 40 CFR §261.33, that the materials are not yet within the RCRA regulatory system when shipped to West Point from the branch operations. We agree with your reasoning that West Point is "the place where the goods become a waste."

I trust this interpretation will be helpful. If I can be of further assistance, please let me know.

Sincerely yours,

Alan S. Corson
Chief
Waste Characterization Branch
Hazardous and Industrial Waste Division (WH-565)

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MSD
MERCK
SHARP
DOHME

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 ultimately disposed of as a

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hazardous waste. Accordingly, we have established procedures to segregate the return goods so that proper disposal can be assured.

One of our products was listed as an acutely hazardous waste (P025) on May 9, 1980 but was reclassified as a toxic waste (U245) on November 25, 1980. Since it was unknown at the time the regulations went into effect whether or not the return goods shipment to West Point contained more than 1 kilogram of that product each month, it was determined that each of our branch operations facilities should register as a generator and a treatment, storage, disposal facility (TSDF). This included notification of all ten EPA Regional Administrators. The TSDF portion of the notification has since been withdrawn based on an evaluation of our standard operating procedures. We have not withdrawn the generator notification because we are not sure if the branch operation facility is a generator of hazardous waste or if the West Point plant is the generator of hazardous waste for that fraction of return goods ultimately disposed as hazardous waste.

In the comments preceding the regulations, the EPA stated that “any material which is intended to be or is in fact thrown away, abandoned or destroyed is a “waste”. (emphasis added). Because most return goods are discarded, it remains unclear to us whether or not the “intent to discard” language in the preamble to the regulations means that the branches' return shipments to West Point, in the absence of the small quantity provisions, would be subject to the requirements of Parts 263 and 264. If branches are generators we face the probability that we will have to establish different return goods procedures for branches located in states whose regulations vary from the federal ones. The resulting loss in uniformity would present increased potential of security and administrative problems.

However, since branches have authority only to return the goods to West Point and only the West Point site has authority to actually discard the goods, we believe that it is reasonable to regard West Point as the place where the goods become a waste. This interpretation is consistent with the regulations' purpose of assuring proper disposal of wastes, since all return goods are tracked under our internal system and the disposal of goods would be managed in compliance with hazardous waste regulations where applicable. Following this approach, we would not have to establish different compliance procedures in different states according to their generator standards, and we could maintain a uniform procedure. Uniformity in procedures results in better security and control, which, in turn, helps to assure compliance with the hazardous waste regulations.

U.S. Environmental Protection Agency

March 25, 1981

As it is our objective to comply with the hazardous waste regulations, we would appreciate your review of our situation to determine whether our 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, Environmental Facilities
Engineer, Facilities Engineering

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