

9455.1991(02)

OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

MAY 16 1991

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 more product-like than waste-like (until a determination is made to dispose of them) because recycling by use/reuse is generally a viable option. If the underlying assumption is that the returned products will be recycled, until the manufacturer or wholesaler determines otherwise (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,

Original Document signed

Sylvia K. Lowrance
Director
Office of Solid Waste