



Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Director

July 28, 2003

Ms. Dana Carder
President
Kellcor USA Ltd.
PO Box 7123
High Point, NC 27264-7123

Re: Handling By-product of Pharmaceutical Returns

Ms. Carder:

This response is to a letter received on June 12, 2003 asking for approval of a process for Reverse Distribution of pharmaceutical returns from long-term care industries and pharmacies that serve practice settings. The pharmaceutical returns may be credit worthy or non-credit worthy, but in all cases are not salable or unusable. The pharmaceutical products may be returned for several reasons: 1) expired in original manufacturer's container, 2) soon to be expired in the original manufacturer's container, and 3) not in the original manufacturer's container and previously dispensed. You state that the pharmacies will seek some type of credit for returns that were not dispensed. You also state that your waste management program includes waste characterization of non-credit worthy pharmaceutical returns, regulatory compliance, and placement in an approved container, storage and transportation to an approved disposal facility. It was also stated in a phone call that the time from pick up to disposal would be less than six months. Acute hazardous waste cannot be stored in a volume greater than one kilogram per month.

Under 40 CFR 261.33 as adopted by reference at 15A NCAC 13A .0106, such returned products are not considered solid waste until a determination has been made to discard the material. We understand that the decision to discard is made by Kellcor at the time it receives the return. Given the information stated above, the North Carolina Hazardous Waste Section (NC HWS) approves Kellcor USA LTD's proposed process. If the above information changes, Kellcor is to notify the NC HWS within 60 days prior to the change taking place. The NC HWS can revisit this approval process at anytime in the future.

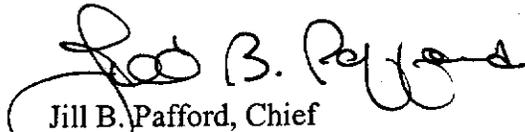
Please note that the NC HWS does not intend for hazardous waste brokers to use reverse distribution systems to relieve generators of the responsibility for making a waste

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determination for discarded material. It is the generator's responsibility to properly identify secondary materials. Also, reverse distribution systems cannot be used as a waste management service to customers/generators without the applicable regulatory controls being in place.

If there are any further questions please call Ann Preston at (919) 733-2178 ext. 230.

Sincerely,


Jill B. Pafford, Chief
Hazardous Waste Section

cc: Ann Preston
Jesse Wells
Mike Williford
Doug Holyfield
Central files

rc: Helen Cotton
Lebeed Kady
Doug Roberts