

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

July 10, 1990

Zulma Nazario
Assistant Director
Caribbean Bioresearch, Inc.
El Retiro Industrial Zone
P.O. Box 325
San German, PR 00753

Dear Ms. Nazario:

Thank you for your letter of May 8, 1990, regarding compliance with the 40 CFR Part 259, Standards for the Tracking and Management of Medical Wastes. After reviewing the information submitted in your letter, it appears that Caribbean Bioresearch, Inc., does generate regulated medical wastes (RMW) which are subject to the Part 259 regulations.

I have enclosed for your convenience a copy of the Part 259 regulations for medical waste management. Section 259.10(a) defines medical waste as "solid waste generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals." The term solid waste includes solid, semisolid, or liquid materials. However, regulated medical waste is a subset of the total medical waste stream.

The classes of medical wastes regulated by EPA under Part 259 are listed in Section 259.30(a). These classes are:

- 1) Cultures and Stocks - Cultures and stocks of infectious agents and associated biologicals, including; cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate and mix cultures.
- 2) Pathological wastes - Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy or other medical procedures and specimens of body fluids and their containers.

- 3) Human Blood and Blood Products - Liquid waste human blood; products of blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components and their containers which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.
- 4) Sharps - Sharps that have been used in animal or human patient care or treatment or in medical, research or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
- 5) Animal Wastes - Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
- 6) Isolation Wastes - Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
- 7) Unused Sharps - The following unused discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

EPA regulates these wastes under Part 259 when generated in a “covered state”, such as Puerto Rico, where Caribbean Research, Inc., is located.

Your letter contains a list of many medical products which are tested at Caribbean Bioresearch, Inc. Many of the wastes generated in the testing of biological. (i.e., preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto) and pharmaceuticals such as antibiotics, injectables, eye drops and ointments would be subject to the Part 259 regulations as Class 1, 3, and 4 RMW. Animal wastes (i.e., animal carcasses, bedding and body parts) generated during testing of biologicals (i.e., Lethal Dose 50, Eye and Skin Irritation tests) could be Class 5 regulated medical wastes.

Please contact Florida Forestier from the Environmental Quality Board in Puerto Rico to assist you in making facility specific determinations regarding the regulatory status of particular wastes generated at Caribbean Research, Inc.

The Part 259 regulations require RMW to be tracked from the point of generation to the point of disposal or the point where the waste has been both “treated and destroyed.” See 40 CFR 259.30 (b)(1)(iv). Treated regulated medical waste is defined under 40 CFR 259.10 as RMW that has been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed. Destroyed RMW is defined as RMW that has been ruined, torn apart, or mutilated, through processes such as, thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as medical waste. It does not mean compaction. Thus a generator of RMW must “treat and destroy” the RMW prior to off-site transport or track the waste from point of generation to point of disposal.

Those liquid wastes which are disposed of through the sewer system are not subject to regulation under Part 259. Please check with the local authorities in regard to any applicable pretreatment or other requirements for such disposal under the Clean Water Act.

Your letter also indicated that Caribbean Bioresearch, Inc., tests cytotoxic drugs. Several cytotoxic drugs are listed hazardous wastes and thus would be subject to RCRA Subtitle C regulations for hazardous waste management when they are discarded.

Samples which are shipped to your facility by a manufacturer for testing become waste when discarded. Therefore, any sample accepted for testing by Caribbean Bioresearch, Inc., which is listed in Section 259.30(a) must be handled and managed as RMW upon disposal. If these materials are shipped back to the manufacturer, the generator must manage them as RMW and comply with all applicable Part 259 regulations.

Medical wastes which are not included in the seven regulated medical waste classes and are not hazardous waste can be disposed of in accordance with applicable solid waste requirements.

If you need further assistance or have other questions please contact the Florida Forestier at 809-722-0437 or Mary Greene at 202-475-7736.

Sincerely,

David Bussard, Director
Characterization and Assessment Division

Attachment

cc: Florida Forester
George Meyers
Estelle Bulka

FaxBack # 11536