

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

September 7, 1990

Eduardo Cordero, P.E.
Syntex (F.P.) Inc.
HC 01 Box 16625
Bo. Mariana Road 909 KM. 1.1
Humacao, Puerto Rico 00661-9731

Dear Mr. Cordero:

Thank you for your letter of May 9, 1990, requesting information on the medical waste regulations applicability to certain wastes generated at your facility. Syntex, Inc., performs quality control procedures on several medical products such as contraceptive pills and anti-inflammatory drugs.

Medical waste as defined in 40 CFR 259.1(b) is "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." Regulated medical waste is a subset of the medical waste stream. Those wastes which are regulated are listed in Classes 1-7 in Section 259.30(a). The quality control procedures you describe would generate regulated medical waste if the products you are testing are being derived from substances extracted from living organisms (e.g., natural progesterone or estrogen or anti-inflammatory agents which are not chemically synthesized). Class 1 regulated medical waste is defined as "Cultures and stocks of infectious agents and associated biologicals, including... wastes from the production of biologicals..." Section 259.10(b) defines biologicals as "preparations made from living organisms and their products, including vaccines, cultures, etc. which are intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto."

Generators of regulated medical wastes (RMW) are subject to the pre-transport requirements such as waste segregation, packaging, labeling and marking, as well as certain generator requirements found in Subpart F of Part 259. RMW must be either "treated and destroyed" or tracked from point of generation to disposal or destruction. While autoclaving constitutes treatment, it would not constitute destruction of RMW.

Destroyed medical waste means "regulated medical waste 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." Destruction of RMW is not required in the Part 259 regulations. However, off-site transport of autoclaved RMW which has not been destroyed would be subject to the Part 259 tracking regulations.

I have enclosed for your convenience a copy of the Part 259 regulations. Please contact Florida Forestier of the Puerto Rico Environmental Quality Board or Mary Greene of my staff at (202) 475-7736 for further assistance.

Sincerely,

David Bussard, Director
Characterization and Assessment
Division

FaxBack # 11556