

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

SEPTEMBER 12, 1989

Dear Mr. Portner:

This letter is in response to your July 10, 1989 letter to Michael Petruska, regarding EPA's medical waste regulations and whether they apply to placenta material which is processed and used for life support purposes.

According to your letter, Roth Products Inc. collects placentas from healthy mothers at hospitals, freezes the placentas, and assembles them for transport to France. In France, a different company processes them to make blood derivatives that are then used for "life giving purposes." The literature that you enclosed, describing the placenta processing at Institute Merieux of Lyon, France, was not received in my office. We are assuming that the placentas are processed to make products that are subsequently used in human health care.

The Federal medical waste regulations at 40 CFR Part 259 apply to "solid wastes" (as that term is defined in the Resource Conservation and Recovery Act (RCRA)), that are also medical wastes and that meet the listing description at 40 CFR 259.30(a). The term "solid waste" means "...discarded material including solid, liquid, semi-solid, and contained gaseous "material resulting from...community activities..." [RCRA Section 1004(27)]. Generally speaking, EPA does not view organs removed from living or deceased humans with the intention of transplanting them, to be "discarded materials." Blood removed from donors that is intended to be processed into materials that will be used for patient care also has not been "discarded." In a similar manner, placentas that will be processed into patient care materials also have not been "discarded." Materials resulting from the transplant or processing activities that are discarded, however, would be "solid wastes."

If you need further assistance, please contact Becky Cuthbertson of my staff at (202) 475-6713.

Sincerely,

Devereaux Barnes, Director
Characterization and Assessment
Division