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

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

Mr. Richard D. Yelvington
Imagination Medical, Inc.
Sales and Marketing Offices
Four Sawgrass Village, Suite 205D
Ponte Vedra Beach. FL 32082

Dear Mr. Yelvington:

Thank you for your letter of January 30, 1997 to Administrator Browner regarding your invention, the Plastic Densification Device (PDD). In your letter you state the PDD is a small, inexpensive device that processes used syringes and lancets to make them safe by encapsulating the sharps and rendering them sterile.

In your letter you state that your technology is an environmentally sound alternative to incineration of this type of medical waste. The Environmental Protection Agency (EPA) is addressing concerns related to the incineration of medical waste. EPA's Office of Air Quality Planning and Standards recently proposed New Source Performance Standards and Emission Guidelines for medical waste incinerators. This proposed regulation sets emission standards for new and existing incineration units. The Clean Air Act requires EPA to develop technology-based standards and guidelines that are based on stringent air pollution controls. These regulations are expected to be promulgated in July 1997. I would like to assure you that there are no existing federal regulations which state that combustion is the only acceptable means of disposing of medical waste. Currently, regulation concerning the disposal of medical waste is at the State level.

In your letter you also state that you are experiencing difficulty with the Food and Drug Administration (FDA) application process for this device. Your letter asserts that units similar to the PDD have been accepted by the Occupational Safety and Health Administration (OSHA) and EPA for 30 years. I would like to clarify that neither EPA nor OSHA approve nor endorse treatment technologies for medical waste. Only devices that use chemicals and claim antimicrobial activity are required to register with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for a label claim. The PDD does not appear to fall into this category.

Currently, many States have established or are establishing a medical waste

treatment technology approval process. However. it is our understanding that until a medical device is approved by FDA it cannot be marketed nor sold. Therefore, the FDA is the appropriate agency for providing assistance in approving your unit. You may wish to contact Mr. Timothy A. Ulatowski at the FDA to further discuss your concerns. He can be reached at:

Timothy A. Ulatowski
Director for General Devices
Food and Drug Administration
9200 Corporate Blvd., Room 350K
Rockville, Maryland 20850
(301) 443-8879

Thank you for your interest in the sound management of medical waste.

Sincerely,

Elizabeth A. Cotsworth, Acting Director
Office of Solid Waste