RFD-94-16

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7

Food and Drug Administration
Rockville MD 20857

November 7, 1994

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[ ]

13-01 Pollitt Drive
Fairlawn, New Jersey 07410

Re: Request For Designation
Lidocaine-Epinephrine Iontophoretic Drug Delivery System [ ]
Our File: RFD-94-16

Dear Dr. [ ]

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on September 7, 1994. In your request, you describe the [ ] System as a product comprised of two major components: a controller [ ] and a patch prefilled with a lidocaine-epinephrine drug specifically formulated for iontophoretic administration. The product may be marketed [ ] or in a [ ] system in which the patch would be disposable and the unit would be refillable with a replacement patch. systems are intended for use to deliver controlled amounts of lidocaine and epinephrine for local anesthesia [ ]

[ ] recommended that primary responsibility for the premarket review and regulation of both the [ ] and the refillable system be assigned to the Center for Drug Evaluation and Research (CDER). For the refillable system, [ ] also requests clarification of the applicable marketing authorities for both systems.

After carefully considering the information provided in the above-referenced request, and consulting with appropriate agency officials in CDER and the Center for Devices and Radiological Health (CDRH), I am in substantial agreement with [ ] recommended disposition of this combination product. Therefore, I am designating CDER as the agency component with primary jurisdiction for the premarket review and regulation of the product. [ ]

[ ] For the refillable system, with disposable patch, the drug components will be regulated under the new drug provisions, and the

device components will be regulated under the premarket notification requirements of Section 510(k) of the Act (21 U.S.C. § 360(k)).

Clinical investigations of [ ] systems should be conducted in accordance with the investigational new drug (IND) provisions of the law (21 U.S.C. 355(i); 21 C.F.R. Part 312); a separate application for an investigational device exemption for the device components will not be necessary.

The Pilot Drugs Evaluation Staff in CDER will be the primary review division and will consult with review team members in CDRH, as necessary. For further information, please contact Ms. Leslie Vaccari, Consumer Safety Officer, CDER/PDES (HFD-7), 5600 Fishers Lane, Rockville, MD 20857, or at 301-443-3741. Please include a copy of this designation letter in your initial submission to CDER.

You may request reconsideration of this designation within 15 days of receipt of this letter. See 21 CFR § 3.8(c). If you have any questions concerning this matter, please do not hesitate to contact Ms. Andrea Chamblee of this office at 301-443-1306.

Sincerely yours,

Amanda B. Pedersen

Amanda B. Pedersen
Chief Mediator and Ombudsman

cc: Leslie Vaccari