RFD-95-03

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

May 12, 1995

Ms. Mirka Dunn
Acting Director
Alza Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

Re: Request For Designation
[ ] fentanyl)
Our File: RFD-95-03

Dear Ms. Dunn:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on March 13, 1995. The [ ] (fentanyl)) is comprised of two components: an [ ] subassembly [ ] [ ] electronic components, such as [ ] [ ] battery, [ ] in a housing), and a drug component subassembly (anode and cathode electrodes, hydrogels for the anode (containing fentanyl) and cathode in a housing, with a [ ] skin adhesive). The components are fully integrated and the product is disposable after it becomes inoperable, 24 hours after usage. [ ] (fentanyl) is intended for use to deliver controlled amounts of fentanyl for management of acute pain.

Alza recommended that primary responsibility for the premarket review and regulation of the [ ] (fentanyl) be assigned to the Center for Drug Evaluation and Research (CDER), and specifically requested that the review be conducted by CDER's Pilot Drug Evaluation Staff.

After 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 agree with Alza's recommended disposition of this combination product, [ ] (fentanyl). Therefore, I am designating CDER as the agency component with primary jurisdiction for the premarket review and regulation of the product. [ ] (fentanyl) will be regulated by CDER under the new drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355; 21 C.F.R. Part 314).

Clinical investigations of the product 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 on the device component. For further information, please contact Mr. David Morgan, Consumer Safety Officer, CDER Pilot Drugs Evaluation Staff (HFD-7), 5600 Fishers Lane, Rockville, MD 20857, or at 301-443-4250. Please include a copy of this designation letter in your initial submission to CDER.

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
Chief Mediator and Ombudsman

cc: Mr. Morgan