RFD 93-09

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7
301-443-1306

Food and Drug Administration
Rockville MD 20857

July 26, 1993

[redacted]
Executive Director
U.S. Pharmaceutical Regulatory Affairs
The Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

Re: Request for Designation
Alprostadil with Self-Injection System
Our file: RFD-93-09

Dear Dr.[redacted]

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on May 27, 1993.

The combination product under consideration is intended to be used in the treatment and diagnosis of erectile dysfunction, and consists of an ampoule of alprostadil sterile solution and a single use, self-injection system. You recommended that clinical investigations of the combination product be conducted under an application for an investigational new drug (IND) and assigned for review to the Center for Drug Evaluation and Research (CDER), Division of Medical Imaging, Surgical and Dental Drug Products.

After considering the information you have submitted and conferring with CDER and the Center for Devices and Radiological Health (CDRH), I substantially concur with your recommendation. I am designating CDER as the agency component with primary jurisdiction for the premarket review and regulation of this combination product. The alprostadil sterile solution component of the product will be reviewed and regulated under the drug authorities of the act (21 U.S.C. § 355). [redacted] Any clinical investigation of the product should be submitted to CDER under an application for an IND (21 C.F.R. Part 312). You do not need to file a separate application for an investigational device exemption.

The Division of Metabolism and Endocrine Drug Products, (HFD-510), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, will be the primary reviewing division. CDER

will consult with CDRH as necessary on issues that relate to the self-injection system. For further information, please contact Mr. Stephen Trostle, Consumer Safety Officer, at 301-443-3520. Please submit a copy of this designation letter in your initial submission to CDER.

Please note that the Prescription Drug User Fee Act of 1992 applies to certain new drug applications filed after September 1, 1992. For additional information about user fees, contact the Office of Small Business, Scientific and Trade Affairs at 301-443-6776.

If you have any questions concerning this matter, please do not hesitate to telephone me or Ms. Suzanne O'Shea of this office, at 301-443-1306.

Sincerely yours,

Amanda B. Pedersen
Product Jurisdiction Officer

cc: Mr. Stephen Trostle