



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food and Drug Administration  
Rockville MD 20857

May 28, 1992

Handwritten marks: a vertical line on the left and several bracket-like symbols in the center.

Re: Request for Designation for SonoRx  
Our File RFD: 92-12

Dear Mr. [ ]

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on April 8, 1992.

SonoRx is an orally administered ultrasound product containing simethicone and cellulose. The product is intended to

After considering the information you have submitted and conferring with the two affected centers, I am designating the Center for Drug Evaluation and Research (CDER) as the agency component with primary jurisdiction for the premarket review and regulation of the product. We also have determined that your product will be regulated under the new drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355; 21 C.F.R. Part 314). Any clinical trials conducted to support a new drug application for the product must be conducted in accordance with the investigational new drug regulations in 21 C.F.R. Part 312.

The Division of Medical Imaging, Surgical and Dental Drug Products in CDER will be the primary reviewing division. For further information, please contact Ms. Susan Kummerer at (301) 443-3560.

Please note that you may request reconsideration of this designation decision under the provisions of 21 C.F.R. §3.8(c). A request for reconsideration must be submitted within 15 days of your receipt of this letter.

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If you have any other questions concerning this matter, please do not hesitate to telephone me, or the Acting Deputy, Mr. Steve Unger at (301) 443-1306.

Sincerely yours,

A handwritten signature in black ink that reads "Amanda B. Pedersen". The signature is written in a cursive style with a long horizontal flourish at the end.

Amanda B. Pedersen  
Product Jurisdiction Officer