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

August 24, 1992

Jack W. Reich, Ph.D.
Vice President Regulatory Affairs
Gensia Pharmaceuticals, Inc.
11025 Roselle Street
San Diego, California 92121-1204

Re: Request for Designation for GenESA (Arbutamine Injection System)
Our File RFD(I): 92-19

Dear Dr. Reich:

This responds to your letter of June 16, 1992, requesting verification of the Agency's handling of the above-referenced product. GenESA is a combination product utilizing a device component to deliver the drug arbutamine as a pharmacological adjunct for the diagnosis of coronary artery disease. Your letter asks for confirmation of your understanding that FDA will review this combination product under an [ ] application [ ] followed by a new drug application (NDA). In addition, your letter states your understanding that jurisdiction for review and approval of the GenESA system has been assigned to the Center for Drug Evaluation and Research (CDER).

After considering the information you have submitted and conferring with the two affected centers, I am confirming that clinical trials may continue under [ ] in support of an NDA for the GenESA system and that CDER will have primary jurisdiction for the premarket review and regulation of this product. The Division of Cardio-Renal Drug Products in CDER will remain the primary reviewing division, and the appropriate contact person is Mr. Gary Buehler at (301) 443-4730.

Based on your interactions with the Agency to date, I also confirm that the GenESA system may be submitted to CDER under an NDA alone. I would like to suggest, however, that you consider submitting to CDER a combined submission that would include an NDA for arbutamine injection and a PMA for the device components of the system. Given the options available to you in this transition period, I strongly recommend that you request a meeting with the Division of Cardio-Renal Drug Products to discuss these options and

the most appropriate format to facilitate the review of the marketing application.

In either case, CDER will consult with the Center for Devices and Radiological Health regarding the device components of the system. In addition, the GenESA system will be subject to all pertinent new drug and device provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351 et. seq., including provisions governing good manufacturing practices and post-marketing reporting.

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

Sincerely yours,

Amanda B. Pedersen
Product Jurisdiction Officer

cc: Gary Buehler ✓