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

October 26, 1992

Sponsor:
Seikagaku Corporation
Tokyo Yakugyo Building 1-5
Nihonbashi-Honcho 2-Chrome
Chuo-Ku, Tokyo
103 Japan

Re: ARTZ
Our File: RFD 92-20

Dear [redacted]

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on August 26, 1992. ARTZ is an injectable product comprised of a purified form of [redacted]. The product is intended to be injected into the knee joint [redacted] to [redacted] and to [redacted]

After considering the information you have submitted and conferring with the two affected centers, I concur in your recommendation and am designating the Center for Devices and Radiological Health (CDRH) as the agency component with primary jurisdiction for the premarket review and regulation of this product.

The product will be regulated under the device provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360 et seq.). Any proposed clinical investigations should be conducted in accordance with the IDE requirements in 21 C.F.R. Part 812.

The Division of General and Restorative Devices in CDRH will be the primary reviewing division. For further information, please contact Dr. Nirmal K. Mishra at (301) 427-1036.

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

Sincerely,

Amanda B. Pedersen
Chief Mediator and Ombudsman

cc: Dr. Nirmal K. Mishra