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 17, 1992

Dr. Robert C. A. Frederickson
Gliatech, Inc.
23420 Commerce Park Road
Cleveland, Ohio 44122

Re: Gliatech [ ]
[ ]
Our File: RFD-92-15

Dear Dr. Frederickson:

On April 15, 1992, Gliatech was notified that the above-referenced [ ] dated March 12, 1992, presented a jurisdictional question. On May 6, 1992, Gliatech submitted a Request for Designation. Subsequently, Gliatech's counsel, [ ] Esq., requested a meeting, and in a letter dated July 7, 1992, agreed to extend the decision date until July 23, 1992.

We have reviewed the information submitted in Gliatech's Request for Designation, as supplemented in our meeting of July 9, 1992. We have determined that your product will be regulated as a medical device under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360c et seq. The Center for Devices and Radiological Health (CDRH) will have primary jurisdiction. The 30-day period for CDRH's review of the above-referenced [ ] will begin on the date of this letter. Should you have any questions, please contact Mr. Mark N. Melkerson, Orthopaedic Devices Branch, CDRH, at (301) 427-1036.

If you have any other questions concerning this matter, please do not hesitate to telephone me at (301) 443-1306.

Sincerely yours,

Amanda B. Pedersen
Products Jurisdiction Officer

cc: [ ]