DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

March 23, 1998

Elyse Wolff
Regulatory Project Leader
Atrix Laboratories, Inc.
2579 Midpoint Drive
Fort Collins, CO 80525-4417

RE: Request for Designation
Atrisorb-D Barrier Kit
Our File: RFD 98-02

Dear Ms. Wolff:

We have completed our review of the above-referenced request for a product jurisdiction determination, which was filed on January 21, 1998.

The Atrisorb-D Barrier Kit is, according to the request for designation, "a sterile, single-use patient kit which aids in the regeneration and integration of periodontal tissue components." The kit consists of a two syringe system [ ]. One of the syringes contains a polymer formulation and the other an antibiotic, doxycycline hyclate. As proposed for use, contents of the two syringes would be blended and the resulting formulation used to form a barrier by precipitation of the formulation [ ]. The barrier is trimmed ex vivo and surgically placed over the periodontal defect.

Atrix currently markets Atrisorb Bioabsorbable Guided Tissue Regeneration (GTR) Kit which, like the Atrisorb-D Barrier Kit, is intended to treat periodontal disease. According to the request, the new product differs from the marketed product "in that doxycycline, a well characterized antibiotic, is added to the ... formulation prior to barrier formation." The request states that the doxycycline is added to the barrier to reduce the risk of bacterial colonization of the barrier once implanted.

Atrix recommended that the Atrisorb-D Barrier Kit be assigned to the Center for Devices and Radiological Health (CDRH) to be regulated under the medical device provisions of the law.

We have carefully considered the information provided in the above-referenced request, and consulted with appropriate officials in CDRH and the Center for Drug Evaluation and Research (CDER). We conclude that the product is a combination of drug and device components whose primary mode of action is that of a physical barrier intended to promote bone regeneration. As we find that the primary mode of action of the product is that of the device component, primary review responsibility for the product is assigned to CDRH. The product will be reviewed and regulated under the medical device provisions of the Federal Food, Drug and Cosmetic Act.

Assignment of review responsibility to CDRH is consistent with the provisions of the CDER-CDRH Intercenter Agreement, which assigns CDRH responsibility for the premarket review and regulation of devices incorporating a drug component with the combination product having the primary intended purpose of fulfilling a device function. See the Intercenter Agreement at section VII.A.2.

The Division of Dental, Infection Control and General Hospital Devices in CDRH will be the primary reviewing group for the product. The CDRH group will conduct its review in collaboration with staff in CDER. For further information about the structuring of this review, contact Mary S. Runner, D.D.S., Branch Chief, Dental Devices Branch, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation, CDRH, 9200 Corporate Boulevard (HFZ-480), Rockville, MD 20850, or telephone at 301-443-8879.

Please include a copy of this letter in your initial submissions to CDRH.

If you have any questions about this letter, contact Steve Unger, of this office, at 301-827-3390.

Sincerely Yours,

Steve Unger for

Amanda Bryce Norton
Chief Mediator and Ombudsman

cc: Mary S. Runner, D.D.S.