DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-751/S-011

Cheri Jones, M.S., R.A.C.
Vice President, Regulatory Affairs
Atrix Laboratories, Inc.
2579 Midpoint Drive
Fort Collins, CO 80525

Dear Ms. Jones:

Please refer to your supplemental new drug application dated February 18, 2003, received February 20, 2003, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Atridox (Atrigel Delivery System with 10% Doxycycline Hyclate).

This supplemental new drug application provides for a change in the storage statement of the drug product to 2^0C-30^0C, with an expiration date of 18 months.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the pouch, immediate container and carton labels).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Frank Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wilson H. DeCamp
6/20/03 11:23:05 AM
approved