DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-751/S-009

Atrix Laboratories, Inc.
Attention: Larry Tamura
Director, Regulatory Affairs
2579 Midpoint Drive
Fort Collins, CO 80525-4417

Dear Mr. Tamura:

Please refer to your supplemental new drug application dated July 31, 2002, received August 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atridox (doxycycline hyclate) 10%, in the Atrigel® Delivery System.

Please also refer to our Approvable Letter dated December 15, 2002.

We acknowledge receipt of your submission dated January 22, 2003.

Your submission of January 22, 2003, constituted a complete response to our December 15, 2002, action letter.

This "Changes Being Effected" supplemental new drug application provides for a change to the Dosage and Administration Section, Product Administration. Specifically, the current language: "Cover the pockets containing ATRIDOX™ with either Coe-Pak™ periodontal dressing or Octyldent™ dental adhesive" is replaced by "Cover the pockets containing ATRIDOX® with either Coe-Pak™ periodontal dressing or a cyanoacrylate dental adhesive."

We completed our review of this application, as amended. 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) as submitted on January 22, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-751/S-009." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
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/

Jonathan Wilkin

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