



NDA 50-783/S-002

Collagenex Pharmaceuticals, Inc.
Attention: Christopher Powala, Senior Director
Drug Development and Regulatory Affairs
41 University Drive, Suite 200
Newtown, PA 18940

Dear Mr. Powala:

Please refer to your supplemental new drug application dated October 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Periostat® (doxycycline hyclate tablets) 20 mg.

Please also refer to our letter dated March 28, 2003.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the Carcinogenesis, Mutagenesis, Impairment of Fertility sub-section of the Precautions Section of the Package Insert per our letter dated March 28, 2003.

We acknowledge receipt of your submission dated February 27, 2004.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL - Package Insert) submitted on October 15, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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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/

Stanka Kukich

3/31/04 10:24:50 AM

Sign off for Dr. Jonathan Wilkin, Division Director