



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-781/S-012

OraPharma, Inc.
Attention: Jackie Linse
Sr. Director, Regulatory Affairs
732 Louis Drive
Warminster, Pa 18974

Dear Ms. Linse:

Please refer to your supplemental new drug application dated August 27, 2007, received August 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARESTIN® (minocycline hydrochloride) Microspheres, 1 mg.

We acknowledge receipt of your submissions dated January 30 and February 4, 2008.

This supplemental new drug application provides for changes to the package insert as follows:

- Addition of language regarding Hypersensitivity Reactions and Autoimmune Syndromes in the PRECAUTIONS section.
- Addition of clarifying language about the post-treatment period in the PRECAUTIONS/Information for Patients subsection.

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 enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplement NDA 50-781/S-012."

If you have any questions, please call Kalyani Bhatt, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director,
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Stanka Kukich
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