DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050808/S-015

SUPPLEMENT APPROVAL

Medicis Pharmaceutical Corporation
Attention: Diane Stroehmann
Director, Regulatory Affairs
7720 North Dobson Road
Scottsdale, AZ 85256

Dear Ms. Stroehmann:

Please refer to your Supplemental New Drug Application (sNDA) dated December 16, 2010, received December 16, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Solodyn (minocycline HCl) Extended Release Tablets, 45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg, and 135 mg.

This "Prior Approval" supplemental new drug application proposes revisions to the container labels for the 45 mg, 65 mg, 90 mg, 115 mg, and 135 mg strengths of Solodyn Extended Release Tablets.

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed container labels as soon as they are available, but no more than 30 days after they are printed.

REPORTING REQUIREMENTS

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 Cristina Attinello, Regulatory Project Manager, at (301) 796-3986.

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:
Container Labeling

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
04/20/2011