DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-808/S-007

APPROVAL LETTER

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

Dear Ms. Stroehmann:

Please refer to your supplemental new drug application dated February 29, 2008, received February 29, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solodyn® (minocycline HCl) Extended Release Tablets, 45, 90, and 135 mg for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

We acknowledge receipt of your submissions dated March 27, July 10 and 14, 2009.

Your submission of March 27, 2009 constituted a complete response to our March 18, 2009 action letter.

This supplemental new drug application provides for the addition of 65 and 115 mg strengths of Solodyn® (minocycline HCl) Extended Release Tablets.

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, text for the patient package insert, immediate container and carton labels) and/or submitted labeling (package insert submitted July 14, 2009, patient package insert submitted July 14, 2009, immediate container and carton labels submitted May 27, 2009).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-808/S-007**." Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available.

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 Sue Kang, Regulatory Project Manager, at (301) 796-4216.

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: 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

7/23/2009 10:12:11 AM