

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**50-808**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-808

Medicis Pharmaceutical Corporation  
Attention: R. Todd Plott, M.D.  
Vice President, Clinical Research and Regulatory Affairs  
8125 North Hayden Road  
Scottsdale, AZ 85258

Dear Dr. Plott:

Please refer to your new drug application (NDA) dated June 30, 2005, received July 8, 2005, submitted pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Solodyn™ (minocycline hydrochloride) Extended Release Tablets 45 mg, 90 mg and 135 mg.

We acknowledge receipt of your submissions dated August 26, September 2, October 3 and 14, November 16, December 22, 2005; January 16, February 8 (facsimile), 10, 15, 16, 17, 22 (two) and 28 (two), March 1, 3, 10, 14, 22, and 30, April 6, 7, 10, 13, 20, 21, 24, and 28, May 8, 2006.

This new drug application provides for the use of Solodyn™ (minocycline hydrochloride) Extended Release Tablets, to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

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 container labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

We are waiving the pediatric study requirement for ages 0 to 11 years for this application.

We remind you of your postmarketing study commitments in your facsimile dated April 20, 2006. These commitments are listed below.

1. Submit results of ongoing 2-year, open-label safety study (MP-0104-07) and the 2-year open-label growth study in pediatric subjects within 3 months after study completion to the Agency.

Protocol Submission: August 2, 2003  
Study Start: Study is ongoing  
Final Report Submission: May 2007

2. Conduct an appropriately designed human spermatogenesis study to evaluate effects of minocycline on male spermatogenesis within 3 months of drug approval and submit results to agency within 3 months after study completion. The spermatogenesis study should be appropriately representative of US demographics and should include a more racially diverse population.

Protocol Submission: December 16, 2005  
Study Start: September 2006  
Final Report Submission: December 2007

3. Evaluation of the carcinogenicity of minocycline HCl in mice.

Protocol Submission: May 2006  
Study Start: November 2006  
Final Report Submission: November 2009

4. Evaluation of the carcinogenicity of minocycline HCl in rats.

Protocol Submission: May 2006  
Study Start: November 2006  
Final Report Submission: November 2009

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print.

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Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
Food and Drug Administration  
5901-B Ammendale  
Beltsville, MD 20705-1266

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  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Felecia Curtis, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

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

Enclosure