



NDA 20-846/S-001

Novartis Pharmaceuticals Corporation  
Attention: Patricia McGovern  
Associate Director, Regulatory Affairs  
59 Route 10  
East Hanover, New Jersey 07936-1080

Dear Ms. McGovern:

Please refer to your supplemental new drug application dated October 22, 1998, received October 23, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lamisil® (terbinafine gel) DermGel, 1%.

We acknowledge receipt of your submissions dated December 15 and December 16, 1998.

This supplemental new drug application provides for the use of Lamisil DermGel for tinea cruris.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The following underlined changes are revisions in the enclosed labeling text for the Adverse Reactions section and Microbiology sub-section:

The last sentence in the Adverse Reactions section, "Skin discoloration consisted of hyperpigmentation which may be related to the healing process of the skin." has been revised to read, "Skin discoloration consisted of hyperpigmentation which resolved in 1 patient during the trial. No follow-up information was available on the remaining 2 patients."

In the Microbiology sub-section, the sentence, "However the clinical significance of the in vitro data is unknown." should read, "However, the clinical significance of the in vitro data is unknown."

These revisions are terms of the approval and should be made in the final printed labeling (FPL)..

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-846/S-001

NDA 20-846/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies until December 2, 2000. However, in the interim, please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at [www.fda.gov/cder/pediatric](http://www.fda.gov/cder/pediatric)) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a

Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity [NOTE: You should still submit a pediatric drug development plan.] and we will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic and Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research