DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-385

Mylan Pharmaceuticals, Inc.
Attention: Andrea B. Miller, R.Ph., Esq.
Executive Director, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, West Virginia 26504-4310

Dear Ms. Miller:

Please refer to your new drug application (NDA) dated September 28, 2001, received September 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ERTACZO™ (sertaconazole nitrate) Cream, 2%.

Please also refer to your October 9, 2003, response to our July 26, 2002, action letter.

We acknowledge receipt of your submissions dated October 24, December 2, 5, 8 and 9 (facsimiles), 2003.

The October 9, 2003, submission constituted a complete response to our July 26, 2002, action letter.

This new drug application provides for the use of ERTACZO™ (sertaconazole nitrate) Cream, 2%, for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older, caused by *Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum*.

We have completed our review of this application, as amended. It 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, immediate container and carton labels). Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you of your postmarketing study commitment in your submission dated December 5, 2003 (facsimile). This commitment is listed below.

Commitment/Study Description: Conduct a dermal carcinogenicity study.

Commitment Category: Non-Clinical Toxicology:

Protocol Submission:	by March 10, 2004.
Study start:	by December 10, 2004
Final report submission:	by December 10, 2007

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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

With regards to the pharmacokinetic data, for this and future NDA's, we encourage you to conduct future *in vivo* bioavailability trials under maximum use conditions in patients with the desired indication. In general, such studies should enroll a sufficient number of subjects (generally >15) to assure the proper characterization of circulating drug levels where feasible. The use of pooled data from mixed indications, although allowed in the past, does not represent current thinking in this area.

For this and future NDAs, we ask that any future clinical studies be designed to establish a correlation between clinical and microbiological outcomes. These studies should include *in vitro* susceptibility evaluations of the relevant fungal pathogens isolated from a sufficient number of patients enrolled. The *in vitro* susceptibility studies must demonstrate the fungicidal activity of the test drug against all relevant pathogens for the requested indications. While data from animal models may help evaluate the equivalent human clinical dose, and pre-clinical *in vitro* susceptibility results may demonstrate the spectrum of activity of the test drug against selected fungal strains, the *in vitro* susceptibility to the test drug of the causative pathogens isolated from the target site in patients enrolled in clinical trials helps confirm microbiological and clinical efficacy.

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

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, please call Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonca Bull, M.D.
Office Director
Office of Drug Evaluation V

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonca Bull

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