

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**50-802**

**APPROVAL LETTER**



NDA 50-802

Barry Calvarese, M.S.  
Vice President, Regulatory and Clinical Affairs  
Dow Pharmaceutical Sciences (Agent for Medicis Pharmaceutical Corporation)  
1330 Redwood Way  
Petaluma, CA 94954-1169

Dear Mr. Calvarese:

Please refer to your new drug application (NDA) dated February 6, 2004, received February 9, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ZIANA™ (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel.

We acknowledge receipt of your submissions dated July 14, August 8, August 11, August 22, August 24, August 28, August 31 (two), September 6, September 7, September 14, October 2, and October 17, 2006.

This new drug application provides for the use of ZIANA™ (clindamycin phosphate 1.2% and tretinoin 0.025%) Gel for the treatment of acne vulgaris.

The May 5, 2006 submission constituted a complete response to our December 7, 2004 action letter.

We 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 and the immediate container and carton labels submitted November 06, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert(s) directly to:

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

If you have any questions, call Shalini Jain, Regulatory Project Manager at (301) 796-0692.

Sincerely,

*{See appended electronic signature page}*

Susan Walker, M.D.  
Division Director  
Division of Dermatology & Dental Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure

Appears This Way  
On Original

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

/s/

-----  
Susan Walker

11/7/2006 04:02:16 PM

Appears This Way  
On Original