DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-819 **NDA APPROVAL**

Dow Pharmaceutical Sciences, Inc.
Attention: Barry M. Calvarese, M.S.
Vice President, Regulatory and Clinical Affairs
1330 Redwood Way
Petaluma, CA 94954-7121

Dear Mr. Calvarese:

Please refer to your new drug application (NDA) dated December 21, 2007, received December 26, 2007 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Acanya™ (clindamycin phosphate 1.2% and benzoyl peroxide 2.5%) Gel. This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated February 7, 11, 19 and 29, March 17, April 9 and 21, May 7, June 19, July 7 and 23, August 6, 11, 13, 18, 22 and 25, September 3, 15, 19 and 29, October 3, 7, 17, 21 and 23, 2008.

This new drug application provides for the use of Acanya™ (clindamycin phosphate 1.2% and benzoyl peroxide 2.5%) Gel for the treatment of acne vulgaris in patients 12 years or older.

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 enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 50-819."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).*

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 50-819**." Approval of this submission by FDA is not required before the labeling is used.

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

We acknowledge your September 3, 2008 request for exemption from the barcode requirement for the clindamycin phosphate solution vial. CDER's Office of Compliance will notify you in a separate communication as to the whether your request is granted.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 11 years because necessary studies are impossible or highly impracticable. This is because the number of children with acne vulgaris in this age group is too small to study.

We note that you have fulfilled the pediatric study requirement for ages 12 to 16 years for this application.

POSTMARKETING COMMITMENTS

We remind you of your postmarketing study commitment in your submission dated October 3, 2008. This commitment is listed below.

1. To conduct a 'maximum use systemic exposure (MUSE)' bioavailability study in the targeted patient population to determine the extent of systemic absorption of the active ingredients in Acanya™ Gel. Elements of the said study should include:

    a) Highest frequency of dosing in the proposed label for Acanya™ Gel
    b) Greatest duration of dosing in the above mentioned labels
    c) Use of to-be-marketed formulation
    d) Maximum total involved surface area to be treated at one time per labeling
    e) Amount applied per square centimeter to be documented
    f) Method of application/site preparation should be documented
    g) Sensitive and validated analytical method to measure active and potential metabolite(s).

Final study protocol submitted:	by February 1, 2009
Patient accrual initiated:	by May 1, 2009
Study completion:	by August 1, 2009
Final report submission:	by February 1, 2010

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 should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Tamika White, Regulatory Project Manager, at (301) 796-0310.

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

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

10/23/2008 09:21:27 AM