



Dow Pharmaceutical Sciences, Inc.

The D in Topicals R&D

Since 1977

Via Federal Express

03 October 2008

Susan J. Walker, MD, Director
Division of Dermatological and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Subject: New Drug Application No. 050819 – Acanya™ Gel
SN0022 – Response to FDA Request for Information

Product: Acanya™ (Clindamycin Phosphate and Benzoyl Peroxide) Gel
1.2% and 2.5%

Indication: Acne Vulgaris

Sponsor: Dow Pharmaceutical Sciences, Inc. (DPSI)

Dear Dr. Walker:

On 21 December 2007, pursuant to §505(b)(2) of the Federal Food, Drug, and Cosmetic Act, and in accordance with Title 21 of the Code of Federal Regulations §314.50, Dow Pharmaceutical Sciences, Inc. (DPSI) submitted original New Drug Application (NDA) 050819 for Acanya™ (Clindamycin Phosphate and Benzoyl Peroxide) Gel, 1.2% and 2.5%, also known as Clindaben™ Gel or IDP-110 Gel.

Reference is made to the October 1, 2008 FDA e-mail request asking the Sponsor to review and respond to the postmarketing commitment contained in the communication. In the communication, the Agency requested that the Sponsor send a letter providing the commitment as outlined in the FDA correspondence and requested receipt of the written response no later than 3:00 p.m. (EDT) on October 6, 2008.

DPSI respectfully submits a written response to the Agency's postmarketing request as:

DPSI Response to FDA Request for Postmarketing Commitment Dated October 1, 2008

Susan J. Walker, MD
Page 2

This amendment is being submitted entirely electronically on one (1) CD. In addition, hard copy versions and original signatures are provided for the following documents for archival purposes:

- Cover letter
- Form FDA 356h
- Form FDA 3674

DPSI considers all the information contained in this application proprietary and confidential. Please be advised that the confidentiality of all enclosed information is provided for under 18 USC, §1905 and/or 21 USC, §331j.

If you have questions regarding the content of this submission, please contact me at 707-793-2600 or at bcalvarese@dowpharmsci.com.

Sincerely,



Barry M. Calvarese, MS
Vice President Regulatory and Clinical Affairs

Enclosures

**DPSI RESPONSE TO FDA POSTMARKETING COMMITMENT REQUEST
RECEIVED OCTOBER 1, 2008**

1.0 FDA REQUEST

The Agency has the following postmarketing request:

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

Send a letter stating the commitment as outlined above, and your agreement to the commitment and timetables. We request receipt of your written response no later than 3:00 p.m. on October 6, 2008.

2.0 DPSI RESPONSE TO FDA REQUEST

The Sponsor accepts and affirms the commitment to conduct a Phase 4 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™ (Clindamycin Phosphate and Benzoyl Peroxide) Gel; to include the elements outlined above, and to be conducted according to the dates specified in the timetable paragraph preceding this paragraph in Section 1.0 – FDA Request.



**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODEIII**

FACSIMILE TRANSMITTAL SHEET

DATE: September 26, 2008

To: Barry M. Calvarese, MS, Vice President, Regulatory and Clinical Affairs.	From: Tamika White, Regulatory Project Manager
Company: Dow Pharmaceutical Sciences, Inc.	Division of Dermatology and Dental Products
Fax number: 707-793-0145	Fax number: 301-796-9894/9895
Phone number: 707-793-2600 x601	Phone number: 301-796-2110
Subject: NDA 50-819 Information Request	

Total no. of pages including cover: 3

Comments:

Review the attached request for information and respond no later than 3:00 p.m. on September 30, 2008.

Document to be mailed: YES NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 796-0310. Thank you.

NDA 50-819

Please refer to your December 21, 2007, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Acanya (clindamycin phosphate and benzoyl peroxide) Gel 1.2%/2.5%.

We have the following information requests:

1. Remove " — gel" modifier from the trade name.
2. Amend the presentation of your trade name, established name, dosage form and strength in all container/closure systems as follows:

Acanya
(Clindamycin Phosphate and Benzoyl Peroxide) Gel
1.2% and 2.5%

3. Provide the color mock ups of the container/closures with indicated changes.

We request receipt of your written response as soon as possible but no later than 3:00 p.m. on September 30, 2008.

If you have any questions, call Tamika White, Regulatory Project Manager, at 301-796-0310.

b(4)

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

/s/

Tamika White
9/26/2008 04:27:00 PM
CSO



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation ODEIII

FACSIMILE TRANSMITTAL SHEET

DATE: September 9, 2008

To: Barry M. Calvarese, MS, Vice President, Regulatory and Clinical Affairs	From: Tamika White, Regulatory Project Manager
Company: Dow Pharmaceutical Sciences, Inc.	Division of Dermatology and Dental Products
Fax number: 707-793-0145	Fax number: 301-796-9895
Phone number: 707-793-2600 x601	Phone number: 301-796-2110
Subject: NDA 50-819 Information Requests	

Total no. of pages including cover: 3

Comments:

Review the attached request for information and respond no later than 3:00 p.m. on
September 16, 2008.

Document to be mailed: YES NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED
AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM
DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you
are hereby notified that any review, disclosure, dissemination, copying, or other action based on the
content of this communication is not authorized. If you have received this document in error, please
notify us immediately by telephone at (301) 796-0310. Thank you.

NDA 50-819

Please refer to your December 21, 2007, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TRADENAME _____ Gel (1.2% clindamycin phosphate, 2.5% benzoyl peroxide).

b(4)

We are reviewing your submission and have the following information requests.

1. Provide a table describing clinical study results from the two pivotal trials of the following:
TRADENAME Gel vs. Vehicle Gel – comparison at 12 weeks of
 - a. skin irritation (sum of itching, burning and stinging);
 - b. erythema; and
 - c. scaling

2. Provide the NDC # on the clindamycin phosphate solution container label.

We request receipt of your written response no later than 3:00 p.m. on September 16, 2008.

If you have any questions, call Tamika White, Regulatory Project Manager, at 301-796-0310.

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

/s/

Tamika White
9/9/2008 02:32:18 PM
CSO