

Initial Quality Assessment  
Branch III  
Pre-Marketing Assessment Division II

**OND Division:** Division of Dermatology and Dental Products  
**NDA:** 50-819  
**Applicant:** Dow Pharmaceutical Sciences, Inc.  
**Stamp Date:** Dec. 26, 2007  
**PDUFA Date:** Oct. 26, 2008  
**Trademark:** \_\_\_\_\_  
**Established Name:** Clindamycin Phosphate and Benzoyl Peroxide  
**Dosage Form:** Gel  
**Route of Administration:** Topical  
**Indication:** Acne Vulgaris  
  
**PAL:** Shulin Ding

b(4)

	YES	NO
<b>ONDQA Fileability:</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Comments for 74-Day Letter</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Summary and Critical Issues:**

**A. Summary**

Dow Pharmaceutical Sciences is submitting a 505(b) (2) New Drug Application (NDA) for the prescription use of Clindaben (1.2% clindamycin phosphate, 2.5% benzoyl peroxide) gel in the treatment of acne vulgaris. The reference listed drug is BenzaClin® topical gel.

The proposed drug substance, \_\_\_\_\_ benzoyl peroxide USP, is referenced to DMF \_\_\_\_\_ held by \_\_\_\_\_ DMF \_\_\_\_\_ was most recently reviewed in August 2007 for ANDA \_\_\_\_\_, Clindamycin-Benzoyl Peroxide Gel, and deemed inadequate to support the ANDA.

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The proposed drug substance, clindamycin phosphate USP, is referenced to DMF \_\_\_\_\_ held by \_\_\_\_\_ and DMF \_\_\_\_\_ held by \_\_\_\_\_. Both DMFs \_\_\_\_\_ have been reviewed multiple times (most recently for the approved NDA \_\_\_\_\_), and deemed adequate to support referenced submissions.

The proposed drug product is an aqueous gel which is prepared by pharmacists at the time of dispensing using a kit which is manufactured by the NDA applicant. The kit consists of two components: clindamycin phosphate \_\_\_\_\_ and benzoyl peroxide \_\_\_\_\_. Clindamycin phosphate \_\_\_\_\_ is packaged at the fill size of 10 mL \_\_\_\_\_. Benzoyl peroxide \_\_\_\_\_ is packaged at the fill size of 40 grams in a \_\_\_\_\_. At the time of dispensing, clindamycin phosphate \_\_\_\_\_ is added to the \_\_\_\_\_ jar containing benzoyl peroxide \_\_\_\_\_, and mixed until homogeneous. The mixing is conducted by a pharmacist for at least 1.5 minutes using a \_\_\_\_\_ spatula included in the kit. The resultant gel (50 g) contains 1.2% of clindamycin phosphate, 2.5% benzoyl peroxide, and the following

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6 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

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Shulin Ding  
2/14/2008 03:53:12 PM  
CHEMIST

Moo-Jhong Rhee  
2/19/2008 09:56:58 AM  
CHEMIST  
Chief, Branch III