DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090785

Cobrek Pharmaceuticals, Inc.
Attention: James L. Kadow
Vice President, Regulatory Affairs
3315 Algonquin Road, Suite 310
Rolling Meadows, IL 60008

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 26, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clindamycin Phosphate Foam, 1%.

Reference is also made to your amendments dated April 2, and June 15, 2009, and February 19, March 15 and March 17, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Clindamycin Phosphate Foam, 1%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Evoclin Foam, 1%, of Stiefel Laboratories, Inc. (Stiefel)

The reference listed drug (RLD) upon which your ANDA is based, Stiefel's Evoclin Foam, 1%, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 7,141,237 (the '237 patent) and 7,374,747 (the '747 patent) are scheduled to expire on January 23, 2024, and August 9, 2026, respectively.

These two patents were listed after the submission of your ANDA. With respect to both patents, you amended your ANDA to contain paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clindamycin Phosphate Foam, 1%, under this ANDA. You have notified the agency that Cobrek Pharmaceuticals, Inc. (Cobrek) complied with the requirements of section 505(j)(2)(B) of the Act.[1]

We note that the '237 and '747 patents were filed with the Secretary not later than 60 days after the enactment of the QI Supplemental Funding Act of 2008 (QI Act). The QI Act provides that with respect to patent information filed with the Secretary within the 60-day period after enactment –

> each applicant that, not later than [February 5, 2009], amends an application that is, on or before [October 8, 2008], a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain [a paragraph IV certification] with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j).

Therefore, with this approval, Cobrek is eligible for 180 days of generic drug exclusivity for Clindamycin Phosphate Foam, 1%.[2] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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[1] For the reasons explained in the agency's March 17, 2009 response to a citizen petition submitted by Stiefel regarding your ANDA, regardless of whether litigation for infringement was initiated by Stiefel within 45 days of receipt of notification of the paragraph IV certification, your ANDA is not subject to a 30-month stay of approval. See Docket No. FDA-2009-P-0120.

[2] See part (b) of section 4 of the QI Supplemental Funding Act of 2008 (QI Act). These Transitional Rules provide that, with respect to patent information filed with the Secretary within the 60-day period after enactment of the QI Act --
"each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the enactment of this Act, a substantially complete application … to contain a [paragraph IV certification] with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)."

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that

version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 090785".***

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| ANDA-90785 | ORIG-1 | COBREK PHARMACEUTICALS INC | CLINDAMYCIN PHOSPHATE |

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

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/s/

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ROBERT L WEST
03/31/2010
Deputy Director, for Gary Buehler