DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078337

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 June 14, 2006 and determined to be acceptable for filing on August 10, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Betamethasone Valerate Foam, 0.12%.

Reference is also made to your amendments dated September 29, 2006; August 9, September 11, and October 1, 2007; April 30 and May 20, 2008; March 18, August 17, and December 18, 2009; April 9 and July 29, 2010; October 11 and November 6, 2011; and January 11, May 30, and October 17, 2012.

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 Betamethasone Valerate Foam, 0.12%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Luxiq Foam, 0.12%, of Stiefel Laboratories, Inc. (Stiefel).

The RLD upon which you have based your ANDA, Stiefel's Luxiq Foam, 0.12%, 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. 6,126,920 (the '920 patent) and 7,078,058 (the '058 patent) are scheduled to expire on March 1, 2016, and May 24, 2017, respectively.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Betamethasone Valerate Foam, 0.12%, under this ANDA. You have notified the agency that Cobrek Pharmaceuticals Inc. (Cobrek), formerly Pentech Pharmaceuticals (Pentech), complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Pentech for infringement of the '920 and '058 patents within the statutory 45-day period in the United States District Court for the Northern District of Illinois [Connectics Corporation and Stiefel Research Australia PTY. Ltd. v. Pentech Pharmaceuticals, Inc., Civil Action No. 07-c-6297], and that the litigation was dismissed.

With respect to 180-day generic drug exclusivity, we note that Cobrek was the first ANDA applicant for Betamethasone Valerate Foam, 0.12%, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Cobrek may be eligible for 180 days of generic drug exclusivity for Betamethasone Valerate Foam, 0.12%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). (b) (4) The agency is not, however, making a formal determination at this time of Cobrek's eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Cobrek begins commercial marketing of Betamethasone Valerate Foam, 0.12%, or (b) at any time prior to the expiration of the '058 patent if Cobrek has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

As of October 1, 2012, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on Oct. 1, 2012, your ANDA is now subject to a backlog fee. You will not be penalized until the backlog fee payment is overdue. As indicated in the Federal Register (FR) notice (77 FR 65199), published on October 25, 2012, the backlog fee is due no later than 30 days after publication of the notice. If you have not paid the fee by the due date, statutory penalties take effect. At that time, FDA

cannot receive any further ANDAs or supplements from Cobrek or its affiliates, and Cobrek will be placed on a publicly available arrears list until the fee is paid.

In addition, your ANDA is now subject to facility fee(s). As noted above, you must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by the date listed in the Federal Register notice announcing the facility fee amount. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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.

Please 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
Office of Prescription Drug Promotion
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 Office of

Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] 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 (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

11/26/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.