DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201402

Perrigo Company
U.S. Agent for: Perrigo Israel Pharmaceuticals, Ltd.
Attention: Valerie Gallagher
Director, Regulatory Affairs
502 Eastern Ave., Plant 6
Allegan, MI 49010

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 25, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clobetasol Propionate Foam (Emollient Formulation), 0.05%.

Reference is made to the tentative approval letter issued by this office on September 27, 2011, and to your amendment dated July 18, 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 Clobetasol Propionate Foam (Emollient Formulation), 0.05%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Olux E Foam, 0.05%, of Stiefel Laboratories, Inc. (Stiefel).

The RLD upon which you have based your ANDA, Stiefel's Olux E Foam, 0.05%, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, U.S. Patent Nos. 6,730,288 (the '288 patent) and 7,029,659 (the '659 patent) are scheduled to expire on September 8, 2019.

With respect to each of these patents, your ANDA contains 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 Clobetasol Propionate Foam, 0.05% (Emollient Formulation), under this ANDA. You notified the agency that Perrigo complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '288 and '659 patents was brought against Perrigo in the United States District Court for the District of Delaware [Stiefel Laboratories, Inc. and Stiefel Research Austrailia PTY. Ltd. v. Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company, Civil Action No. 10-cv-00592-UNA]. You have also notified the agency that the case has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Perrigo Israel Pharmaceuticals, Ltd. (Perrigo) was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the listed patents. Therefore, with this approval, Perrigo is eligible for 180 days of generic drug exclusivity for Clobetasol Propionate Foam (Emollient Formulation), 0.05%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from 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.

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/UCM072392.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

08/14/2012

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