DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-763

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 27, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clobetasol Propionate Foam, 0.05%.

Reference is also made to the tentative approval letter issued by this office on August 30, 2006, and to your amendments dated January 20, 2006; November 6, 2007; and February 12, and February 27, 2008.

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, 0.05%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Olux Foam, 0.05%, of Connetics Corporation.

The reference listed drug (RLD) upon which you have based your ANDA, Olux Foam, 0.05%, of Connetics Corporation, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,126,920 (the '920 patent), is scheduled to expire on October 3, 2017.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '920 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clobetasol Propionate Foam, 0.05%, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action was brought against the former holder of this ANDA, Agis Industries Ltd (Agis) and/or the current holder, Perrigo Israel Pharmaceuticals Ltd. (Perrigo) for infringement of the '920 patent that was the subject of the paragraph IV certification. This action must be brought against Agis/ Perrigo prior to the expiration of 45 days from the date the notice you provided under Section 505 (j)(2)(B) was received by the NDA/patent holder. You have notified the agency that Agis/Perrigo complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Agis for infringement of the '920 patent within the statutory 45-day period in the United States District Court for the District of New Jersey [Connetics Corporation and Connetics Australia PTY LTD. v AGIS Industries (1983) LTD, Civil Action No. 05 Civ. 5038 (HAA)]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Agis/Perrigo was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '920 patent. Therefore, with this approval, Perrigo is eligible for 180 days of generic drug market exclusivity for Clobetasol Propionate Foam, 0.05%. 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.

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.

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.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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
3/10/2008 08:42:22 AM
for Gary Buehler