DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-223

Actavis Mid Atlantic LLC
Attention: Janak Jadeja, R.Ph.
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 24, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clobetasol Propionate Lotion, 0.05%.

Reference is also made to the tentative approval letter issued by this office on May 29, 2008, and to your amendments dated May 26, 2006, and August 25, October 10, November 18, and November 25, 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 Lotion, 0.05%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clobex Topical Lotion, 0.05%, of Galderma Laboratories LP. (Galderma).

The RLD upon which you have based your ANDA, Galderma's Clobex Topical Lotion, 0.05%, 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. 6,106,848 (the '848 patent) is scheduled to expire on September 22, 2017.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '848 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clobetasol Propionate Lotion, 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 an action was brought against Actavis Mid Atlantic LLC (Actavis) for infringement of the listed '848 patent. You have notified the agency that Actavis complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '848 patent was brought against Actavis within the statutory 45-day period in the United States District Court for the Northern District of Texas, Fort Worth Division [Galderma Laboratories, L.P. and Galderma S.A. v. Actavis Mid Atlantic, L.L.C., Civil Action No. 4-06CV-471-Y]. 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 Actavis was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '848 patent for this drug product. Therefore, with this approval, Actavis is eligible for 180 days of generic drug exclusivity for Clobetasol Propionate Lotion, 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.

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
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/oc/datacouncil/spl.html, 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 78-223".***

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
12/4/2008 09:20:35 AM
Deputy Director, for Gary Buehler