DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078854

Actavis Mid Atlantic LLC
Attention: Elizabeth Trowbridge, R.A.C.
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 30, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Clobetasol Propionate Shampoo, 0.05%.

Reference is also made to your amendments dated August 16, 2007; January 8, January 9, and January 21, February 27 (2), and March 13, 2008; August 28, and December 9, 2009; March 18, April 29, May 3, August 27, and September 10, 2010; and March 9, and April 13, 2011.

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 Shampoo, 0.05%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clobex Shampoo, 0.05%, of Galderma Laboratories L.P. (Galderma).

The RLD upon which you have based your ANDA, Galderma's Clobex Shampoo, 0.05%, 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. 7,316,810 (the '810 patent) and 7,700,081 (the '081 patent) are scheduled to expire on June 17, 2019 and January 3, 2022, respectively.

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clobetasol Propionate Shampoo, 0.05%, under this ANDA. You have notified the agency that Actavis Mid Atlantic LLC (Actavis) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Actavis for infringement of the '810 patent 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, LLC, Civil Action No. 4-08-cv-115-A]. You have notified the agency that Actavis entered into a settlement agreement with Galderma and that the litigation has been dismissed.

With respect to 180-day generic drug exclusivity for Clobetasol Propionate Shampoo, 0.05%, Actavis was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '810 and '081 patents. The agency notes that Actavis failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. We have determined, however, that this was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed. Specifically, during its bioequivalence review, the agency asked Actavis to perform comparative vasoconstrictor bioassay studies; the agency later told Actavis the agency was reviewing the appropriateness of vasoconstrictor bioassay studies for topical corticosteroid drug products that are applied to the hirsute scalp.

Therefore, with this approval, the agency has determined that Actavis is eligible for 180 days of generic drug exclusivity for Clobetasol Propionate Shampoo, 0.05%. Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in that section. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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.

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}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

06/07/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.