DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 201000

ANDA APPROVAL

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 12, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Adapalene Gel, 0.3%.

Reference is made to the tentative approval letter issued by this Office on October 17, 2012. We acknowledge your amendment dated March 22, 2013. We also acknowledge receipt of your correspondences dated September 18, and 22, 2014, addressing the patent issues noted below.

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 Adapalene Gel, 0.3% to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Differin Gel, 0.3%, of Galderma Labs L.P.

The RLD upon which you have based your ANDA, Differin Gel, 0.3%, of Galderma Labs L.P., is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
7,579,377 (the '377 patent)	February 23, 2025
7,737,181 (the '181 patent)	August 29, 2024
7,834,060 (the '060 patent)	March 12, 2023
7,838,558 (the '558 patent)	March 12, 2023
7,868,044 (the '044 patent)	March 12, 2023
8,703,820 (the '820 patent)	March 12, 2023

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Adapalene Gel, 0.3%, 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 for infringement of the '377 and the ‘181 patents was brought against Actavis within the statutory 45-day period in the United States District Court for the District of Delaware [Galderma Laboratories, L.P., Galderma S.A., and Galderma Research & Development, S.N.C. v. Actavis Mid Atlantic LLC, Civil Action No. CA 10-CV-0045]. You have also notified the agency that the case has been dismissed. The agency notes that the '060, '558, '044, and '820 patents were not listed in the Orange Book at the time your ANDA was submitted, and your paragraph IV certifications were submitted in amendments to your ANDA.

With respect to 180-day generic drug exclusivity, Tolmar Inc., was granted 180 days of generic drug exclusivity for Adapalene Gel, 0.3%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, expires on October 25, 2014. We note that there is no longer a 180-day exclusivity bar to the approval of your Adapalene Gel, 0.3%.

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(s) 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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur

by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

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,

William P. Rickman -S

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Office of Generic Drugs
Center for Drug Evaluation and Research