DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 205128

ANDA APPROVAL

Actavis Laboratories UT, Inc.
577 Chipeta Way
Salt Lake City, UT 84108
Attention: Cherri Petrie
Executive Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 20, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5%.

Reference is made to your amendments dated June 4, 2015. Your June 4, 2015 submission constituted a complete response to our March 13, 2015 action letter.

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 Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5% to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Acanya Gel, 1.2%/2.5% of Dow Pharmaceutical Sciences, Inc. (Dow).

The reference listed drug (RLD) upon which you have based your ANDA, Dow's Acanya Gel, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,288,434 (the '434 patent)	August 5, 2029
8,663,699 (the '699 patent)	June 3, 2029
8,895,070 (the '070 patent)	June 3, 2029

Your ANDA contains paragraph IV certifications to the '434 and '699 patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5%, under this ANDA. You have notified the agency Actavis Laboratories UT, Inc. (Actavis) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and litigation for infringement of the '434 and '699 patents was brought against Actavis within the statutory 45-day period in the United States District Court for the for the District of New Jersey

[Dow Pharmaceutical Sciences, Inc. and Valeant Pharmaceuticals North America LLC vs. Watson Laboratories, Inc. Actavis, Inc. And RX Corp., and Watson Pharma, Inc.], Civil Action Nos. 13-cv-06401-SRC-CLW and 14-cv-02661-SRC-CL W].[1] You have notified the Agency that a stipulated consent judgment was entered in both litigations and that the litigations were terminated.

With respect to the '070 patent, FDA has determined that information on this patent was submitted by the NDA holder more than 30 days after the patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(vi), no applicant with an appropriate patent certification at the time of the submission of the patent was required to submit an amended patent certification to address the '070 patent. In addition, you elected not to submit an amended patent certification with respect to this patent.

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 '434 and '699 patents. Therefore, with this approval, Actavis is eligible for 180 days of generic drug exclusivity for Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C 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 FD&C 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

[1] FDA notes that the '699 patent was submitted to the agency after submission of your ANDA, and therefore litigation with respect to this patent created no statutory stay of approval.

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

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2015.06.19 15:21:38 -04'00'

Carol A. Holquist, RPh
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