DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 207238

ANDA APPROVAL

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

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 3, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Diclofenac Sodium Topical Solution, 2% w/w.

Reference is also made to the tentative approval letter issued by this office on October 3, 2016, and to your amendment received on February 23, 2017.

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 Office of Bioequivalence has determined your Diclofenac Sodium Topical Solution, 2% w/w, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Pennsaid Topical Solution, 2% w/w, of Horizon Pharma Ireland Ltd. (Horizon).

The RLD upon which you have based your ANDA, Horizon's Pennsaid Topical Solution, 2% w/w, 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
8,217,078 (the '078 patent)	July 10, 2029
8,252,838 (the '838 patent)	April 21, 2028
8,546,450 (the '450 patent)	August 9, 2030
8,563,613 (the '613 patent)	October 17, 2027
8,618,164 (the '164 patent)	July 10, 2029
8,741,956 (the '956 patent)	July 10, 2029
8,871,809 (the '809 patent)	October 17, 2027
9,066,913 (the '913 patent)	October 17, 2027

9,101,591 (the '591 patent)	October 17, 2027
9,132,110 (the '110 patent)	October 17, 2027
9,168,304 (the '304 patent)	October 17, 2027
9,168,305 (the '305 patent)	October 17, 2027
9,220,784 (the '784 patent)	October 17, 2027
9,339,551 (the '551 patent)	October 17, 2027
9,339,552 (the '552 patent)	October 17, 2027
9,370,501 (the '501 patent)	July 10, 2029
9,375,412 (the '412 patent)	July 10, 2029
9,415,029 (the '029 patent)	July 10, 2029
9,539,335 (the '335 patent)	October 17, 2027

Your ANDA contains paragraph IV certifications to each of the patents[1] 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 Diclofenac Sodium Topical Solution, 2% w/w, under this ANDA. You have notified the Agency that Actavis Laboratories UT, Inc. (Actavis) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated within the statutory 45-day period against Actavis for infringement of the '078, '838, '450, '613, '164, '809, '903, '591, '110, '304, '305, and '784 patents in the United States District Court for the District of New Jersey [Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. v. Watson Laboratories, Inc., Actavis, Inc. and Actavis PLC, Civil Action Nos. 14-cv-07992, 15-cv-05025, 15-cv-06989, 15-cv-07742, and 16-cv-00645]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which 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 for Diclofenac Sodium Topical Solution, 2% w/w. Therefore, with this approval, Actavis is eligible for 180 days of generic drug exclusivity for Diclofenac Sodium Topical Solution, 2% w/w. 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 a correspondence to this ANDA informing the Agency of the date you begin commercial marketing.

Under section 506A of FD&C 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 and 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.

REPORTING REQUIREMENTS

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

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

ANNUAL FACILITY FEES

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 1st 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.

CONTENT OF LABELING

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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

CAPT Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

1 The Agency notes that the '956, '809, '913, '591, '110, '304, '305, '784, '551, '552, '501, '412, '029 and '335 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Carol Holquist

Digitally signed by Carol Holquist
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