



ANDA 202294

ANDA APPROVAL

Par Pharmaceutical Inc.
One Ram Ridge Road
Chestnut Ridge, NY 10977
Attention: Meredith Selby
Senior Director, Regulatory Affairs

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 25, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dexlansoprazole Delayed-Release Capsules, 60 mg.

Reference is also made to the tentative approval letter issued by this office on December 26, 2013, and to your amendments received September 17 and December 17, 2015; February 29, March 15, April 15, and August 12, 2016; and January 11 and March 9, 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 Dexlansoprazole Delayed-Release Capsules, 60 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Dexilant Capsules, 60 mg, of Takeda Pharmaceuticals U.S.A., Inc. (Takeda). Your dissolution testing should be incorporated into the stability and quality control program using the FDA-recommended method and specification for your application (see enclosure).

The RLD upon which you have based your ANDA, Takeda's Dexilant Capsules, 60 mg, 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>U.S. Patent Number</u>	<u>Expiration Date</u>
6,462,058 (the '058 patent)	December 15, 2020*
6,664,276 (the '276 patent)	July 30, 2023*
6,939,971 (the '971 patent)	December 15, 2020*
7,285,668 (the '668 patent)	December 15, 2020*
7,790,755 (the '755 patent)	February 2, 2027*
8,105,626 (the '626 patent)	March 27, 2027*
8,173,158 (the '158 patent)	September 17, 2030*
8,461,187 (the '187 patent)	July 17, 2026*
8,722,084 (the '084 patent)	April 15, 2024*

8,784,885 (the '885 patent)	April 15, 2024*
8,871,273 (the '273 patent)	January 11, 2028
9,011,926 (the '926 patent)	February 24, 2026
9,145,389 (the '389 patent)	June 15, 2020
9,233,103 (the '103 patent)	March 5, 2032
9,238,029 (the '029 patent)	January 17, 2026

* with pediatric exclusivity added

Your ANDA contains paragraph IV certifications to each of the patents¹, 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 Dexlansoprazole Delayed-Release Capsules, 60 mg, under this ANDA. You have notified the Agency that Par Pharmaceutical Inc. (Par) 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 Par for infringement of the '058, '276, '971, '668 and '755 patents in the United States District Court Northern District of California [Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. v. Handa Pharmaceuticals, LLC and Par Pharmaceutical, Inc., Civil Action No. 11-cv-00840] and by Par for non-infringement and invalidity of the '626, '158 and '187 patents in the United States District Court Northern District of California [Par Pharmaceutical, Inc., and Handa Pharmaceuticals, LLC. v. Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceuticals U.S.A., Inc., Civil Action No. 5:13-cv-01927]. You have also notified the Agency that these cases were dismissed.

With respect to 180-day generic drug exclusivity, we note that Par was the first ANDA applicant for Dexlansoprazole Delayed-Release Capsules, 60 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Par may be eligible for 180 days of generic drug exclusivity for Dexlansoprazole Delayed-Release Capsules, 60 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Par failed to obtain tentative approval of this ANDA within 40 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Par's eligibility for 180-day generic drug exclusivity. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Par begins commercial marketing of Dexlansoprazole Delayed-Release Capsules, 60 mg, or (b) at any time prior to the expiration of the '058, '276, '971, '668 and '755 patents if Par has not begun commercial marketing. Please submit correspondence to this ANDA informing the Agency of the date commercial marketing begins.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

¹ The Agency notes that the '626, '158, '187, '084, '885, '273, '926, '389, '103, and '029 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.

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}

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

ENCLOSURE:

DISSOLUTION

The “interim” dissolution specifications are as follows:

Media	Acid Stage: 0.1 N HCl Buffer Stage 1: pH 6.0 Phosphate buffer with 5mM Sodium Lauryl Sulfate Buffer Stage 2: pH 7.4 Phosphate buffer with 5mM Sodium Lauryl Sulfate
Volume	Acid Stage: 500 mL Buffer Stage 1: 700 mL Buffer Stage 2: 900 mL
USP Apparatus	USP II (Paddle)
Speed	75 rpm
Specifications	Acid Stage: NMT ^(b) ₍₄₎ % in 120 minutes Buffer Stage 1: NLT ^(b) ₍₄₎ % in 30 minutes NMT ^(b) ₍₄₎ % in 60 minutes Buffer Stage 2: NLT ^(b) ₍₄₎ % in 60 minutes

The “interim” dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Supplement – Changes Being Effected when there are no revisions to the “interim” specifications or when the final specifications are more stringent than the “interim” specifications. In all other instances, the information should be submitted in a Prior Approval Supplement.



Heidi
Lee

Digitally signed by Heidi Lee
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