DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 202842

ANDA APPROVAL

Par Pharmaceutical, Inc.
One Ram Ridge Road
Chestnut Ridge, NY 10977
Attention: Linda Kulick
Associate Director, Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Dexmethylphenidate Hydrochloride Extended-Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg.

Reference is also made to the complete response letter issued by this office on September 16, 2016, and to your amendments dated October 5 and October 17, 2016.

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 Dexmethylphenidate Hydrochloride Extended-Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Focalin XR Extended-Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg, of Novartis Pharmaceuticals, Corp. (Novartis).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Apparatus	I (basket)	
Speed	100 rpm	
Medium	First 2 hours: 0.01N HCl Hours 2-10: phosphate buffer, pH 6.8	
Volume	Acid 500 mL; buffer 500 mL	
Specifications	Time (hours)	Amount Dissolved (%)
	2	NMT (b)(4)%
	4	NLT (b)(4)%

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 Special Supplement – Changes Being Effected when there are no revisions to the “interim” specifications or when the final specifications are tighter than the “interim” specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Novartis’ Focalin XR Extended-Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg, 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. 6,228,398 (the '398 patent) and 6,730,325 (the '325 patent) are both scheduled to expire on November 1, 2019.

Your ANDA contains paragraph IV certifications to each of the 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 Dexmethylphenidate Hydrochloride Extended-Release Capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 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 against Par for infringement of the '398 and '325 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Elan Corporation, PLC and Elan Pharma International Ltd. v. Intellipharmaceutics Corporation, Intellipharmaceutics Ltd., and Par Pharmaceutical, Inc., Civil Action No. 11-cv-00480 and Alkermes Pharma Ireland Limited v. Par Pharmaceutical, Inc., Civil Action No. 11-cv-1119]. You have further notified the agency that these cases have been dismissed.

With respect to 180-day generic drug exclusivity, we note that Par was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Dexmethylphenidate Hydrochloride Extended-Release Capsules, 25 mg and 35 mg. Therefore, with this approval, Par is eligible for 180 days of generic drug exclusivity for Dexmethylphenidate Hydrochloride Extended-Release Capsules, 25 mg and 35 mg. It is noted that this ANDA was not tentatively approved within the 40[1]-month period described in section 505(j)(5)(D)(i)(iv) of the FD&C Act. Nevertheless, the agency has determined that Par has not forfeited its eligibility for 180-day generic drug exclusivity.[2] This exclusivity, which is provided

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[1] For applications submitted between January 9, 2010, and July 9, 2012 containing a Paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on July 9, 2012, and ending on September 30, 2015, section 1133 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144) extends this period to 40 months. For applications submitted between January 9, 2010, and July 9, 2012 (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on October 1, 2015, and ending on September 30, 2016, section 1133 of FDASIA extends this period to 36 months. In addition, if an application was submitted between January 9, 2010, and July 9, 2012 containing a Paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and FDA has not approved or tentatively approved the application but must consider whether the applicant has forfeited exclusivity because a potentially blocked application is ready for approval, FDA will apply the 40-month period if it makes the forfeiture determination between the period of time beginning on January 9, 2010, and ending on September 30, 2015. For all other applications, the 30-month period set forth section 505(j)(5)(D)(i)(IV) of the FD&C Act applies.

[2] ANDA 202842 was received on January 28, 2011, and amended to include the 35 mg and 25 mg strengths on

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) of the FD&C Act. Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

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

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

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September 29, 2011 and September 30, 2011, respectively. This ANDA was never tentatively approved and therefore was not granted tentative approval within the 40-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the agency has determined that the failure to obtain tentative approval within the 40-month period 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.

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,

{See appended electronic signature page}

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

Carol Holquist

Digitally signed by Carol Holquist
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