



ANDA 202580

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26505

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 9, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg.

Reference is made to the tentative approval letter issued by this office on August 13, 2012, and to your amendments dated May 6, July 26, and August 7, 2013.

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 Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Focalin (XR) Extended-release Capsules, 30 mg, of Novartis Pharmaceuticals Corporation (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:

Dissolution Testing should be conducted in:

Medium: 0.01N HCl for 0-2 hours, followed by Phosphate Buffer, pH 6.8 for 2-6 hours
Apparatus: I (Basket)
Speed: 100 RPM
Temperature: 37°C ± 5°C
Volume: 500 mL (Acid stage); 500 mL (Buffer stage)

Specifications:

Acid stage: 2 hours, (b) (4)
Buffer stage: 2 hours, (b) (4)
4 hours, NLT (b) (4)

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if 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, 30 mg, 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>U.S. Patent Number</u> | <u>Expiration Date</u> |
|------------------------------|------------------------|
| 5,837,284 (the '7284 patent) | Dec 4, 2015 |
| 5,908,850 (the '850 patent) | Dec 4, 2015 |
| 6,228,398 (the '398 patent) | Nov 1, 2019 |
| 6,355,656 (the '656 patent) | Dec 4, 2015 |
| 6,528,530 (the '530 patent) | Dec 4, 2015 |
| 6,635,284 (the '5284 patent) | Dec 4, 2015 |
| 6,730,325 (the '325 patent) | Nov 1, 2019 |
| 7,431,944 (the '944 patent) | Dec 4, 2015 |

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable,

or will not be infringed by your manufacture, use, or sale of Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg, under this ANDA. You have notified the agency that Mylan Pharmaceuticals, Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act. We note that there were no patents for the RLD listed in the Orange Book when the Office of Generic Drugs (OGD) received your ANDA on December 9, 2010. Therefore, the agency has determined that, under these circumstances, a 30-month stay of approval does not apply to this ANDA regardless of patent litigation.¹

With respect to 180-day generic drug exclusivity, we note that Mylan was the first applicant to submit a substantially complete ANDA with a paragraph IV certification for Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg. Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the 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 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

¹ It is noted that in April 2011, litigation for infringement of the '7284, '850, '656, '530, '5284, and '944 patents was initiated against Mylan in the United States District Court for the District of New Jersey, and for infringement of the '398 and '325 patents in the United States District Court for the District of Delaware.

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(1)] 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}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

08/28/2013

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.