DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 079108

Watson Laboratories, Inc.
Attention: Joyce Anne DelGaudio
Executive Director, Regulatory Affairs
Morris Corporate Center III, Building D
400 Interpace Parkway
Parsippany, NJ 07054

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 6, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexmethylphenidate Hydrochloride Extended-release Capsules, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

Reference is made to the complete response letter issued by this office on April 15, 2013, and to your amendments dated May 29, July 1, August 5, and November 11, 2013. Reference is also made to your patent amendment dated November 13, 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. However, we are unable to grant final approval to your Dexmethylphenidate Hydrochloride Extended-release Capsules, 5 mg, 10 mg, 15 mg, and 20 mg, at this time because of the exclusivity issue noted below. Therefore, only your Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg is **approved**. The 5 mg, 10 mg, 15 mg and 20 mg, strengths are **tentatively approved.**

The reference listed drug (RLD) upon which you have based your ANDA is Focalin XR Extended-release Capsules, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg, of Novartis Pharmaceuticals Corp. (Novartis). This RLD 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.S. Patent Number	Expiration Date
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

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is 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 and 20 mg, under this ANDA.[1] You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that within the statutory 45-day period litigation was initiated against Watson:

- for infringement of the '7284, '850, '656, '530, and '5284 patents in the United States District Court for the District of New Jersey [Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma Ag v. Actavis South Atlantic LLC and Abrika Pharmeuticals, Inc., Civil Action No. 07-cv-5367]; and

- for infringement of the '398 and '325 patents in the United States District Court for the District of Delaware [Elan Corporation, PLC and Elan Pharma International Ltd., v. Actavis South Atlantic LLC, Civil Action No. 07-cv-679].

You have further notified the agency that each of these cases has been dismissed.

[1] Watson is not required to certify to the listed patents insofar as the 30 mg strength because these patents are considered late listed as to this ANDA relative to that strength. See 21 CFR 314.94(a)(12)(vi).

I. Approval of Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg

With respect to your Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg, we 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, your Dexmethylphenidate Hydrochloride Extended-release Capsules, 30 mg, 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 RLD, Novartis' Focalin XR, 30 mg. 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:

Apparatus:	USP Apparatus I (basket)
Speed:	100 rpm
Medium 1:	0.01N HCl (first 2 hours)
Medium 2:	Phosphate buffer, pH 6.8 (2-10 hours)
Volume:	500 mL for each medium

Specifications:

Acid Stage:	NMT (b) (4) in 2 hours
Buffer Stage:	(b) (4) in 3 hours*
	NLT (b) (4) in 5 hours*

*Continued time after transfer

These "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.

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 draft or mock-up form, two copies of both the promotional materials and package insert 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.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE."

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.

II. Tentative Approval of Dexmethylphenidate Hydrochloride Extended-release Capsules, 5 mg, 10 mg, 15 mg and 20 mg

Your Dexmethylphenidate Hydrochloride Extended-release Capsules, 5 mg, 10 mg, 15 mg and 20 mg, are **tentatively approved.** This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

We are unable to grant final approval to your Dexmethylphenidate Hydrochloride Extended-release Capsules, 5 mg, 10 mg, 20 mg and 40 mg, at this time because prior to the submission of your paragraph IV certifications, one or more applicants with an ANDA providing for one or more of those four strengths of Dexmethylphenidate Hydrochloride Extended-release Capsules, submitted paragraph IV certifications to one or more of the listed patents. Your ANDA insofar as these strengths will be eligible for final approval on the date that is 180 days after the date the agency receives notice, with respect to the other

ANDA(s), of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act, or exclusivity with respect to each of the strengths is otherwise resolved.

To reactivate your ANDA prior to final approval of the 5 mg, 10 mg, 15 mg and 20 mg strengths, please immediately submit a "***MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED***." This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a ***MINOR AMENDMENT TO ORIGINAL #2 – FINAL APPROVAL REQUESTED***.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practice (cGMP) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes to Original #2, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Andrew Kim, Project Manager, at (240) 276-8438.

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

11/21/2013

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