DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-107

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexmethylphenidate Hydrochloride Tablets, 2.5 mg, 5 mg, and 10 mg.

Reference is made to the tentative approval letter issued by this office on December 29, 2006, and to your amendments dated November 15, 2004, November 4, 2005, and January 11, 2007.

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 Tablets, 2.5 mg, 5 mg, and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Focalin Tablets, 2.5 mg, 5 mg, and 10 mg, respectively, 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 application.

The RLD upon which you have based your ANDA, Novartis' Focalin Tablets, 2.5 mg, 5 mg, and 10 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") for this drug product:

U.S. Patent Number	Expiration Date
5,908,850 (the '850 patent)	December 4, 2015
6,355,656 (the '656 patent)	December 4, 2015
6,528,530 (the '530 patent)	December 4, 2015

With respect to the '530 patent, the agency recognizes that this patent was late listed with respect to your ANDA and no certification is required. See 21 CFR 314.94(a)(12)(vi).

With respect to the '850 and '656 patents, 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 Tablets, 2.5 mg, 5 mg and 10 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against TEVA prior to the expiration of 45 days from the date the notices you provided under section 505(j)(2)(B)(i) were received by the NDA/patent holder(s). You notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and no litigation for infringement was brought against TEVA with respect to the '656 patent. However, litigation was brought against TEVA for infringement of the '850 patent in the United States District Court for the District of New Jersey [Celgene Corporation, Novartis Pharmaceuticals Corporation, and Novartis Pharma AG v. TEVA Pharmaceuticals, Civil Action No. CA #4030 (SRC)]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.[1] Thus, with the expiration of this 30-month period, the agency is able to grant final approval to your ANDA.

[1] Because information on the '850 patent was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

With this approval, TEVA is eligible for 180-day generic drug exclusivity for Dexmethylphenidate Hydrochloride Tablets 2.5 mg, 5 mg, and 10 mg, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in section 505(j)(5)(B)(IV) of the Act. The agency has determined that TEVA was the first ANDA applicant to submit a substantially complete ANDA for Dexmethylphenidate Hydrochloride Tablets 2.5 mg, 5 mg, and 10 mg, containing paragraph IV certifications as noted above. This exclusivity will begin to run from the date of first commercial marketing of the drug, or from the date of a court decision finding the patent invalid or not infringed, whichever event occurs first. Please submit correspondence to your ANDA to inform the agency of the beginning of this 180-day period.

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.

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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/

Gary Buehler

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