DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-287

Teva Pharmaceuticals USA
Attention: Phillip Erickson
Senior Director, Regulatory Affairs
1090 Horsham Road
PO Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 30, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluoxetine Capsules USP, 10 mg and 20 mg.

Reference is also made to the tentative approval letter issued by this office on April 20, 2006, and to your amendments dated February 28, and April 28, 2008. We also refer to your correspondence dated January 25, and November 27, 2007; April 24, and May 6, 2008, addressing patent issues associated with this ANDA which are noted below.

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 Fluoxetine Capsules USP, 10 mg and 20 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Sarafem™ Pulvules® of Lilly Research Laboratories.

The reference listed drug (RLD) upon which you have based your ANDA, Sarafem™ Pulvules®, 10 mg and 20 mg of Lilly Research Laboratories, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) 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
4,971,998 (the '998 patent)	May 20, 2008
5,114,976 (the '976 patent)	November 19, 2009
5,744,501 (the '501 patent)	November 19, 2009

Your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act to the '998 patent, which states that you will not market this drug product prior to the expiration of the patent. The '998 patent, with pediatric exclusivity added, expired on May 20, 2008.

Your ANDA contains paragraph IV certifications to each the '976 and '501 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '976 and '501 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Fluoxetine Capsules USP, 10 mg, and 20 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 is 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 notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Teva complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Teva within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to '976 and '501. Therefore, with this approval, Teva is eligible for 180-days of generic drug exclusivity for Fluoxetine Capsules USP, 10 mg, and 20 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv). Please submit

[1]Because information on '976 and '501 was/were submitted to FDA before August 18, 2003, this is 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).

correspondence to this ANDA informing the agency of the date the exclusivity begins to run.[2]

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 application 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

[2] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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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