DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 75-719

JUN 30 2006

IVAX Pharmaceuticals, Inc.
Attention: Patricia Jaworski
Director, Regulatory Affairs
125 Wells Avenue
Congers, NY 10920

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 11, 1999, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sertraline Hydrochloride Tablets, 25 mg (base), 50 mg (base) and 100 mg (base).

Reference is made to the tentative approval letter issued by this office on December 9, 2004, and to your amendments dated April 6, and May 19, 2000; and March 22, March 23, April 4, April 18, and June 29, 2006.

We have completed the review of this ANDA as amended and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Sertraline Hydrochloride Tablets, 25 mg (base), 50 mg (base), and 100 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Zoloft Tablets, 25 mg (base), 50 mg (base), and 100 mg (base), respectively, of Pfizer Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The referenced listed drug (RLD) upon which you have based your ANDA, Pfizer's Zoloft Tablets, 25 mg (base), 50 mg (base) and 100 mg (base), 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"):

U.S. Patent Number	Expiration Date
4,536,518 (the '518 patent)	June 30, 2006*
4,962,128 (the '128 patent)	May 2, 2010*
5,248,699 (the '699 patent)	February 13, 2013*
5,744,501 (the '501 patent)	January 6, 2009
5,789,449 (the '499 patent)	January 6, 2009

* with pediatric exclusivity added

With respect to the '128, '501, and '449 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act indicating that these are method of use patents that do not claim any indication for which you are seeking approval under your ANDA.

With respect to the '699 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sertraline Hydrochloride Tablets, 25 mg (base), 50 mg (base) and 100 mg (base), under this ANDA. You have notified the agency that IVAX Pharmaceuticals, Inc. (IVAX) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '699 patent was initiated against IVAX in the United States District Court for the District of New Jersey [Pfizer, Inc. v. Zenith Goldline Pharmaceuticals, Inc. and IVAX Corporation, Civil Action No. 00-CV-0408 (pertaining to the 50 mg (base) and 100 mg (base) strengths of the drug product) and Civil Action No. 01-CV-6007 (pertaining to the 25 mg (base) strength of the drug product)]. The cases were consolidated and subsequently dismissed.

With respect to the '518 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that IVAX will not market Sertraline Hydrochloride Tablets, 25 mg (base), 50 mg (base) and 100 mg (base) prior to the expiration of the '518 patent. The '518 patent expired (with pediatric exclusivity added) on June 30, 2006.

Finally, with respect to 180-day generic drug exclusivity, the agency has concluded that IVAX was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '699 patent for this drug product. Therefore, with this approval, IVAX is eligible for 180-days of generic drug exclusivity for Sertraline Hydrochloride Tablets, 25 mg (base), 50 mg (base) and 100 mg (base). 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).[1] 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.

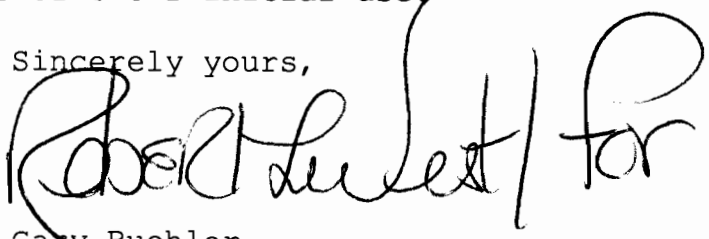
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] 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).