DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-765

MAY 22 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 June 19, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Escitalopram Oxalate Tablets, 5 mg, 10 mg, and 20 mg.

Reference is also made to your amendments dated May 14, and July 14, 2004; February 4, July 14, September 13, September 29, and October 31, 2005; and April 13, 2006. We also acknowledge receipt of your correspondence dated November 6, 2003; September 10, 2004; August 10, October 19, and November 8, 2005, and February 24, and April 13, 2006, addressing the patent and exclusivity issues associated with this ANDA.

We have completed the review of this ANDA 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 Escitalopram Oxalate Tablets, 5 mg, 10 mg, and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Lexapro Tablets 5 mg, 10 mg, and 20 mg, respectively, of Forest Laboratories, Inc. (Forest). 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, Forest's Lexapro Tablets, 5 mg, 10 mg, and 20 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,916,941 (the '941 patent) is scheduled to expire on

January 25, 2023 (with pediatric exclusivity added) and U.S. Patent No. RE34712 (the '712 patent) is scheduled to expire on December 8, 2009 (with pediatric exclusivity added).

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 Escitalopram Oxalate Tablets, 5 mg, 10 mg, and 20 mg, under this ANDA. You further informed the agency that Forest initiated a patent infringement suit against you with respect to the '712 patent in the United States District Court for the District of Delaware [Forest Laboratories, Inc., Forest Laboratories Ireland Ltd, and H Lundbeck A/S v. IVAX Pharmaceuticals, Inc. and Cipla Ltd., Civil Action No. 03-891-JJF]. 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] No litigation was brought against IVAX with respect to the '941 patent.

With respect to 180-day generic drug exclusivity, IVAX was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '941 and '712 patents. Therefore, with this approval IVAX is eligible for 180 days of generic drug exclusivity for Escitalopram Oxalate Tablets, 5 mg, 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 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.

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[1] A February 1, 2006 court order details the extension of the 30-month stay of approval (which would have expired on February 11, 2006) identified in section 505(j)(5)(B)(iii) of the Act through and including the earlier of the date of the completion of the post-trial briefing, which is identified as May 19, 2006, or June 30, 2006.

[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).

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,

Robert Lumpkin for

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