DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-765

IVAX Pharmaceuticals, Inc.
An indirect, wholly owned subsidiary of Teva Pharmaceuticals USA
Attention: Patricia Jaworski
Two University Plaza
Suite 220
Hackensack, NJ 07601

Dear Ms. Jaworski:

This is in reference to your abbreviated new drug application (ANDA) for Escitalopram Oxalate, 5 mg, 10 mg, and 20 mg, which was approved on May 22, 2006, pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act).

The listed drug referenced in your ANDA is Lexapro (Escitalopram Oxalate) Tablets of Forest Laboratories, Inc. (Forest). As you know, there are patents listed for this product in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). At the time your ANDA was submitted, U.S. Patent number RE34,712 (the '712 patent) was listed in the Orange Book with an expiration date of March 12, 2012 (with pediatric exclusivity added).

Your ANDA contained a paragraph IV certification to the '712 patent under section 505(j)(2)(A)(vii)(IV) of the Act. You notified the agency that Forest brought an action for infringement of the '712 patent against IVAX within the statutory 45-day period in the United States District Court for the District of Delaware (*Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF). On February 24, 2006, you notified the agency of a February 1, 2006 court order that extended the 30-month stay of approval 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 was identified as May 19, 2006, or June 30, 2006. You further notified the agency that the post-trial briefing period ended on May 19, 2006, and was not extended. Your ANDA was approved on May 22, 2006.

However, after approval of your ANDA, the district court upheld the validity of the '712 patent. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF (D. Del. July 13, 2006). The decision of the district court was affirmed by the United States Court of Appeals for the Federal Circuit. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 2007-1059 (Fed. Cir. Sept. 5, 2007). In a submission dated November 8, 2007, you amended your patent certification for the '712 patent from a paragraph IV certification to a paragraph III certification.

Section 505(j) does not expressly provide for a change in approval status when the patent litigation results in a finding that one or more listed patents is infringed; however, provisions of the 1984 Drug Price Competition and Patent Term Restoration Act codified in the Patent Code give the court hearing the patent litigation the authority to order the date of approval of an ANDA to be no earlier than the date of expiration of the infringed patent. 35 U.S.C. 271(e)(4).

When a court orders that the approval of an ANDA is not effective before a certain date, FDA may convert an approved ANDA to tentative approval status to reflect the court's order. This interpretation was upheld in November 2004, in *Mylan Laboratories, Inc., v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004). Therefore, after consideration of the district court's July 13, 2006 judgment (and affirmation by the Federal Circuit) that the effective date of approval for the IVAX ANDA be delayed until the expiration of the '712 patent (including all term extensions), FDA is converting the approval of IVAX's Escitalopram Oxalate Tablets, 5 mg, 10 mg, and 20 mg, including all amendments and supplements thereto, to a tentative approval. This change conforms the status of the ANDA to the court's order. A tentative approval will not become final until FDA issues an approval letter. *Barr Labs., Inc. v. Thompson*, 238 F. Supp. 2d 236, 245-50 (D.D.C. 2002) (affirming FDA's decision that an approval with a delayed effective date is tentative).

The agency has found that, based upon the information you have presented, the drug described in your ANDA is safe and effective for use as recommended in the submitted labeling. Your ANDA, therefore, is **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 practices (cGMPs) of the facilities used in the manufacture and testing of the drug products, and is subject to change on the basis of new information that may come to our attention.

Because the agency is granting a **tentative approval** for this ANDA, when you believe that your ANDA may be considered for final approval, you must amend your ANDA to notify the agency whether circumstances have or have not arisen that may affect the effective date of final approval. To reactivate your ANDA, please submit an amendment prior to the date you believe your ANDA will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. The amendment should be designated clearly in your cover letter as a **MINOR AMENDMENT**. In addition to this amendment, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above. Any 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 procedures are subject to agency review before final approval of the ANDA will be made.

The drug products that are the subject of this ANDA may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery or introduction into interstate commerce of this drug before the effective final approval date is prohibited under

section 301(d) of the Act. Also, until the agency issues the final approval letter, these drug products will not be listed in the Orange Book.

Please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (240) 276-9319, for further information regarding this matter.

Sincerely,

{See appended electronic signature page}

Gary J. 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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