ANDA 77-206

Aurobindo Pharma Limited Inc.
Attention: Prasada Kambham
U.S. Agent for Aurobindo Pharma Limited
666 Plainsboro Road, Suite 210
Plainsboro, NJ 08536

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 26, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Sertraline Hydrochloride Tablets 25 mg (base), 50 mg (base), and 100 mg (base).

Reference is made to your amendments dated January 12, June 10, July 29, and August 5, 2005. We also acknowledge receipt of your correspondence dated September 27, and November 9, 2004, regarding the patent issues noted below.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval at this time because of patent issue noted below. Therefore, the ANDA 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 product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your ANDA, Zoloft Tablets of Pfizer Pharmaceuticals, Inc. (Pfizer), is subject to periods of patent protection. The following patents with their expiration dates are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic

Equivalence Evaluations ("the Orange Book") for this drug product:

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

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 under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action is brought against Aurobindo Pharma Limited (Aurobindo) for infringement of the '699 patent that was the subject of the paragraph IV certification. This action must have been brought against Aurobindo prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B) was received by the NDA/patent holder(s). You notified the agency that Aurobindo complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Aurobindo 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 the '128, '501 and '449 patents, your ANDA contains patent statements under section 505(j)(2)(A)(viii) of the Act indicating that the '128, '501 and '449 patents are method of use patents, and that these patents do not claim any proposed indication for which you are seeking approval under your ANDA.

Finally, 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 you will not market this drug product prior to the expiration of the patent. Therefore, final approval of your ANDA may not be made effective pursuant to 21 U.S.C.

[1] Because information on the '699 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) was enacted. See MMA § 1101(c)(3).

355(j)(5)(B)(ii) of the Act until the ‘518 patent has expired, i.e., June 30, 2006.

To reactivate your ANDA prior to final approval, please submit a “MINOR AMENDMENT – FINAL APPROVAL REQUESTED” 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval, and it should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

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 practices (cGMPs) are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either “major” or “minor” changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act and 21 U.S.C. 331(d). Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under 21 U.S.C. 355, and will not be listed in the “Orange Book.” Should you believe that there are grounds for issuing the final approval letter prior to June 30, 2006, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Thomas Hinchliffe, Pharm.D., Project Manager, (301) 827-5771.

Sincerely yours,

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