ANDA 77-670

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

APPLICANT: Lupin Pharmaceuticals,Inc. TEL: 410-576-2000

ATTN: Leslie Sands FAX: 410-576-2221

FROM: Thomas Hinchliffe PROJECT MANAGER: (301) 827-5771

Dear Sir or Madam:

This facsimile is in reference to your abbreviated new drug application dated March 31, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Sertraline Hydrochloride Tablets, 25 mg, 50 mg and 100 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-670

Lupin Pharmaceuticals Inc.
Attention: Leslie Sands
U.S. Agent for: Lupin Limited
Harborplace Tower
111 South Calvert Street, 21st Floor
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2005, 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 the tentative approval letter issued by this office on December 29, 2006, and to your amendments dated October 28, 2005; March 10, 2006; and January 2, 2007.

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 Sertraline Hydrochloride Tablets 25 mg (base), 50 mg (base), and 100 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference 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 application.

The reference listed drug (RLD) upon which you have based your ANDA, Zoloft Tablets of Pfizer Pharmaceuticals, Inc., is subject to periods of patent protection. The following patents with their expiration dates 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
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 was brought against Lupin Limited (Lupin) for infringement of the '699 patent that was the subject of the paragraph IV certification. You notified the agency that Lupin complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '699 patent was brought against Lupin within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

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 these are method of use patents, and that they do not claim any indication for which you are seeking approval under your ANDA.

In addition, the 180-day generic drug exclusivity period, noted in our tentative approval letter of December 29, 2006, that had blocked final approval of your ANDA, expired on February 6, 2007.

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 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
2/6/2007 09:06:15 AM
for Gary Buehler