DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-934

JUN 30 2006

Roxane Laboratories, Inc.
Attention: Elizabeth Ernst
Associate Director, DRA
1809 Wilson Road
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 8, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sertraline Hydrochloride Oral Concentrate, 20 mg (base)/mL.

Reference is also made to our tentative approval letter dated January 20, 2006, and to your amendments dated March 24, April 13, and June 9, 2006.

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 Sertraline Hydrochloride Oral Concentrate, 20 mg (base)/mL, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Zoloft Oral Concentrate, 20 mg (base)/mL, of Pfizer Pharmaceuticals, Inc. (Pfizer).

The referenced listed drug (RLD) upon which you have based your ANDA, Pfizer's Zoloft Oral Concentrate, 20 mg (base)/mL, is subject to periods of patent protection. The following patents and 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 |
|---|---|
| 4,536,518 (the '518 patent) | June 30, 2006* |
| 5,248,699 (the '699 patent) | February 13, 2013* |
| 5,744,501 (the '501 patent) | January 6, 2009 |

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|---|---|
| 5,789,449 (the '449 patent) | January 6, 2009 |
| 6,727,283 (the '283 patent) | October 11, 2019 |

*with pediatric exclusivity added

With respect to the '699 and '283 patents, 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 Sertraline Hydrochloride Oral Concentrate, 20 mg (base)/mL, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Roxane Laboratories, Inc. (Roxane) for infringement of the '699 or '283 patents that were the subjects of the paragraph IV certifications. You have notified the agency that Roxane complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Roxane within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to the '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.

Your ANDA also contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act to the '518 patent. This certification states that you will not market this drug product prior to the expiration of this patent. The '518 patent, with pediatric exclusivity added, expired on June 30, 2006.

With respect to 180-day generic drug exclusivity, Roxane was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '699 and '283 patents. Therefore, with this approval, Roxane is eligible for 180-days of generic drug exclusivity for Sertraline Hydrochloride Oral Concentrate, 20 mg (base)/mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing 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.

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,

Robert LeSet / for

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