ANDA 75-356

July 30, 2003

Apotex Corp.
Attention: Marcy Macdonald
U.S. Agent for: TorPharm
616 Heathrow Drive
Lincolnshire, IL 60069

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Paroxetine Hydrochloride Tablets, 10 mg (base), 20 mg (base), 30 mg (base), and 40 mg (base).

Reference is also made to the tentative approval letters issued by this office on May 24, 2001, and April 4, 2003, and to your amendments dated July 10, July 18, July 21, and July 23, 2003.

The listed drug product (RLD) referenced in your application, Paxil Tablets of GlaxoSmithKline, is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

U.S. Patent	Expiration Date (With Pediatric Exclusivity)
4,721,723	June 29, 2007
5,789,449	July 6, 2009
6,113,944	June 14, 2015
5,872,132	November 19, 2015
5,900,423	November 19, 2015
6,080,759	November 19, 2015
6,133,289	November 19, 2015
6,121,291	September 17, 2017*
6,172,233	July 15, 2018
6,063,927	October 23, 2019

* The ‘291 patent has two separate use codes (U-286 and U-431).

For the remainder of this letter, all references to individual patents will be to the final three digits of the patent number; i.e. the ‘927 patent.

Your application contains paragraph IV certifications to the ‘723, ‘132, ‘423, ‘927, ‘759, ‘944, ‘289, ‘291 and ‘233 patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, sale, or use of Paroxetine Hydrochloride Tablets, 10 mg (base), 20 mg (base), 30 mg (base), and 40 mg (base) will not infringe on these patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against TorPharm for infringement of any of the patents noted in the first sentence of this paragraph which were the subjects of the paragraph IV certifications. Such infringement action(s) must be brought against TorPharm prior to the expiration of forty-five (45) days from the date the individual notices you provided to the NDA/patent holder(s) under paragraph (2)(B)(i) pursuant to each certification were received. You notified the agency that TorPharm complied with the requirements of Section 505(j)(2)(B) of the Act, and that the following patent infringement actions were initiated by the NDA/patent holder(s):

‘723 United States District Court for the Northern District of Illinois (SmithKline Beecham Corp. and Beecham Group, PLC v. Apotex Corp, TorPharm, Inc. and Apotex, Inc. Civil Action No. 98-C-3952);

‘423 United States District Court for the Eastern District of Pennsylvania (SmithKline Beecham Corp. v. Apotex Corp., Apotex, Inc., and Torpharm, Inc. Civil Action No. 99-4304);

‘759 United States District Court for the Eastern District of Pennsylvania (SmithKline Beecham Corp. v. Apotex Corp., Apotex, Inc., and TorPharm, Inc. Civil Action No. 00-CV-4888);

‘944 United States District Court for the Eastern District of Pennsylvania (SmithKline Beecham Corp. and Beecham PLC v. Apotex Corp., Apotex, Inc., and TorPharm, Inc. Civil Action No. 98-C-3952); and

‘233 United States District Court for the Eastern District of Pennsylvania (SmithKline Beecham, PLC v. Apotex Corporation, Apotex, Inc., and Torpharm, Inc. Civil Action No. 01-CV-2169).

With respect to the litigation involving the ‘723, ‘423, ‘759, and ‘944 patents, the Agency recognizes that the 30-month periods identified in Section 505(j)(5)(iii) of the Act, during which time FDA was precluded from approving your application, have expired. You have informed the Agency that no legal action regarding the ‘132, ‘927, ‘291, or ‘289 patents was brought against TorPharm within the respective forty-five day statutory periods. In addition, the Agency has determined that the NDA holder submitted the ‘449 patent to its NDA more than 30-days after this patent was issued by the U.S. Patent and Trademark Office. Therefore, under 21 CFR 314.94(a)(12)(vi), you are not required to submit an amended certification to address this patent.

Please refer to our letter dated July 30, 2003, which explains eligibility for 180-day generic drug exclusivity under Section 505(j)(5)(B)(iv) of the Act for Paroxetine Hydrochloride Tablets, 10 mg (base), 20 mg (base), 30 mg (base), and 40 mg (base). That letter also addresses GlaxoSmithKline’s request dated July 1, 2003, to remove the ‘927, ‘759, and ‘233 patents from the Orange Book.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Paroxetine Hydrochloride Tablets, 10 mg (base), 20 mg (base), 30 mg (base), and 40 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Paxil® Tablets, 10 mg (base), 20 mg (base), 30 mg (base), and 40 mg (base), respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

/s/ “GB”

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