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September 19, 2003

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Via Overnight Courier

Dockets Management Branch
U.S. Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2003P-0408/CP1 (September 2, 2003 Citizen Petition)

On behalf of TorPharm, Inc. ("TorPharm"), the undersigned respectfully submits this comment and supplemental exhibit (Tab A) to TorPharm's September 2, 2003 Citizen Petition requesting that the Commissioner of Food and Drugs ("FDA" or "the Agency") immediately withdraw final approval of Synthon Pharmaceuticals, Ltd.'s ("Synthon") New Drug Application ("NDA") No. 21-299 for Asimia (paroxetine mesylate) 10 mg, 20 mg, 30 mg and 40 mg tablets, submitted under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("the Act").

On September 17, 2003, SmithKline Beecham Corp. ("GSK") served its responses to certain admission requests issued by TorPharm in pending paroxetine patent litigation between the parties, captioned *SmithKline Beecham Corp. v. Apotex Corp.*, Case Nos. 99-4304, 00-4888, 01-159 and 01-2169 (E.D.Pa.) (Surrick, J.) In those responses, which we attach hereto at Tab A, GSK admits, *inter alia*, that:

- GSK "has not granted Synthon Pharmaceuticals, Inc. the right to rely on any [GSK] proprietary data that is disclosed in [GSK's] NDA No. 20-031 in support of Synthon's NDA No. 21-299" (Tab A at 5);

- None of the clinical trials or data disclosed in GSK's NDA No. 20-031 for paroxetine *hydrochloride* tablets used any paroxetine *mesylate* or otherwise determined the safety and efficacy of paroxetine *mesylate* (*Id.* at 2); and

- Prior to January 1, 2002, GSK conducted no clinical trials of any kind with paroxetine *mesylate* (*Id.* at 3-5).

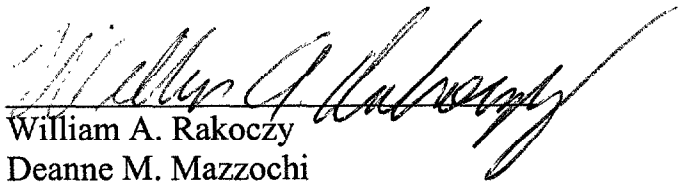
As previously articulated in TorPharm's Petition, on information and belief, Synthon has not conducted any clinical trials to establish the safety and efficacy of paroxetine *mesylate*, much less the rigorous "full investigations" of safety and efficacy required by Section 505(b) of the Act. Rather, it appears that Synthon referenced and FDA relied on the proprietary data in GSK's NDA No. 20-031 for paroxetine *hydrochloride*. But Section 505(b)(2) does not authorize or permit Synthon to reference, and FDA to rely on, GSK's proprietary NDA data. Moreover, as noted above and in the attached response, GSK has not authorized or granted Synthon the right to reference or rely on such data from GSK's NDA.

Even if Synthon could rely on GSK's NDA data for paroxetine *hydrochloride* (it can't), there is no question that GSK's NDA does not contain any clinical data or information establishing the safety and efficacy of paroxetine *mesylate*. So FDA has approved a paroxetine *mesylate* product without any investigations establishing that the *mesylate* product is actually safe or effective. Instead, it appears that FDA approved Synthon's product based on little more than a standard bioequivalence test—precisely the same type of test conducted by Section 505(j) ANDA applicants.

Accordingly, Synthon's application should not have been approved under Section 505(b)(2), which is devoted to new drugs for which full investigations of safety and efficacy are required—of which there were none here for paroxetine *mesylate*. That application should have been reviewed and considered by FDA, if at all, only as an ANDA subject to TorPharm's 180-day exclusivity for paroxetine tablets. Either way, however, final approval of Synthon's application must be immediately withdrawn.

Dated: September 19, 2003.

Respectfully submitted,



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