GPhA
Generic Pharmaceutical Association

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October 9, 2003

Dockets Management Branch
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20857

Re: Docket Number 03P-0408: Comments by the Generic Pharmaceutical Association in Response to Petition Filed by Torpharm, Inc.

The Generic Pharmaceutical Association ("GPhA") submits the following comments in response to the September 2, 2003 Citizen Petition filed by Torpharm, Inc. (Docket No. 03P-0408) ("Torpharm Petition"). The Torpharm Petition seeks FDA's immediate withdrawal of the Agency's final approval of Synthon Pharmaceuticals, Ltd.'s ("Synthon") New Drug Application ("NDA") for Asimia (paroxetine mesylate). In support of its petition, Torpharm makes several arguments, including the argument that a section 505(b)(2) application may not rely on FDA safety and efficacy determinations that are based on non-public data previously submitted to FDA as part of an approved NDA for a brand company reference drug. In this case, Torpharm argues that Synthon relied on FDA determinations of safety/efficacy based on public, non-proprietary data submitted to the Agency by GlaxoSmithKline as part of its approved NDA for Paxil (paroxetine hydrochloride), and that, as a matter of law, a 505(b)(2) application may not rely on such data.

Torpharm's argument is identical to the arguments made in two other FDA Citizens Petitions, filed by Pfizer, Inc. and Pharmacia Corp. FDA Docket Nos. 01P-0323 (July 27, 2001 Citizens Petition of Pfizer, Inc. and Pharmacia Corp.); 02P-0447 (October 11, 2002 Citizens Petition of Pfizer, Inc.). GPhA has submitted two sets of comments to those Petitions addressing and refuting this argument in detail. December 10, 2001 Comments of GPhA in Docket No. 01P-0323, and October 9, 2003 Comments of GPhA in Docket Nos. 01P-0323 and 02P-0447. GPhA hereby incorporates by reference these two sets of GPhA comments and ask that they expressly be made part of this Docket.

For the foregoing reasons, GPhA respectfully requests that FDA reject Torpharm's argument that section 505(b)(2) precludes reliance on Agency determinations of safety and efficacy that are derived from data provided the Agency as part of a reference drug NDA.

Respectfully submitted,

Kathleen D. Jaeger

Kathleen D. Jaeger
President
Generic Pharmaceutical Association

Dated: October 9, 2003