MYLAN LABORATORIES INC.

June 3, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket Number 02P-0256 / CP 1

Dear Madam or Sir:

Nearly one year ago, on May 31, 2002, Mylan Pharmaceuticals Inc. ("Mylan") submitted a citizen's petition pursuant to 21 U.S.C. § 355(j), 21 C.F.R. §§ 10.30, 314.94, 314.50(a)(1) and 314.420(a)(2) and (b), which is docketed at No. 02P-0256 / CP 1 (the "Petition"). Mylan requested in the Petition that the Commissioner determine, on an expedited basis, that Mylan was first to file a substantially complete ANDA for a 45mg strength of mirtazapine hydrochloride (reference drug, Remeron® - Organon). The basis for Mylan's request is that ANDA No. 76-119, when submitted by Teva Pharmaceuticals ("Teva") for filing, did not reference a valid Drug Master File ("DMF") and, therefore, was not substantially complete as required by 21 C.F.R. § 314.101(d). Mylan's ANDA No. 76-122, on the other hand, was substantially complete when submitted and subsequently accepted for filing on February 28, 2001. We continue to believe this issue -- whether an ANDA that references a non-existent DMF is substantially complete and may properly be accepted for filing-- is of substantial importance to the industry and requires an immediate decision.

FDA tentatively approved both Mylan's and Teva's ANDAs on January 15, 2002. The United States District Court for the District of New Jersey issued an opinion on December 18, 2002, granting Mylan's and Teva's motions for summary judgment of non infringement of Organon's U.S. Patent No. 5,977,099 (the"'099 Patent"). Mylan filed its minor amendment requesting final approval of its 45mg Mirtazapine tablets on January 2, 2003. We therefore believe that resolution of the Petition is the only remaining obstacle to FDA granting final approval to Mylan's (or Teva's) ANDA for 45mg mirtazapine tablets.

Mylan has concerns that FDA will issue final approval of Mylan's and Teva's 45mg mirtazapine ANDAs concurrently on June 16, 2003, with neither company being awarded 180 days of marketing exclusivity, or with a retroactive award of exclusivity to one company dating back to December 18, 2002, the date of the court's summary judgment opinion. Both scenarios are inconsistent with the statute and would necessitate immediate judicial intervention.

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If FDA issues multiple approvals and fails to make any decision as to exclusivity or on the issues raised by the Petition, FDA would abrogate its clear statutory mandate to grant exclusivity to the first ANDA filer. Such a decision would also leave unanswered the important question of whether an ANDA that does not reference a valid DMF or references a non-existent DMF is substantially complete.

If FDA issues multiple approvals in June 2003 and awards exclusivity retroactively to December 18, 2002, the exclusivity would be rendered meaningless solely through FDA's inexcusably long delay in deciding the Petition. Further, a retroactive award of exclusivity would be inappropriate because, to date, no judgment has actually been entered by the district court. The plain language of 21 C.F.R. § 314.107(b)(B)(ii) provides that approval is triggered by entry of judgment:

> "If before the expiration of the 30-month period ... the court issues a final order or judgment that the patent is invalid, unenforceable, or not infringed, approval may be made effective ***on the date the court enters judgment.***"

(emphasis supplied).

Because the Petition has been pending for nearly a year without a decision and because we have reason to believe FDA might issue final approval without deciding the important issues raised by the Petition, we request that the Petition be given FDA's immediate and utmost attention. Specifically, Mylan requests that FDA decide that: (1) Teva's ANDA for 45mg generic mirtazapine tablets was not substantially complete when filed; (2) Mylan was the first to file a complete ANDA with respect to the 45mg generic mirtazapine tablets; (3) Mylan's ANDA 76-122 should be granted final approval; and (4) Mylan is entitled to 180 days of marketing exclusivity under ANDA 76-122 to commence on the date the district court enters a final judgment of non-infringement on its docket, or the date Mylan first begins commercial sales.

Very truly yours,

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