

May 29, 2002

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

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### CITIZEN PETITION



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The undersigned, on behalf of a client, submits this petition in triplicate pursuant to 21 U.S.C. 355(j)(2)(C) and 21 CFR 10.30 and 314.93. Petitioner requests that the Food and Drug Administration (FDA) determine that 7.5 mg tablets of Mirtazapine Tablets are suitable for an Abbreviated New Drug Application (ANDA) based on the listed drug Remeron® Tablets, 15 mg.

#### A. ACTION REQUESTED

Petitioner seeks a determination that a 7.5 mg Mirtazapine Tablet drug product is suitable for an ANDA based on the listed drug Remeron® Tablets, 15 mg.

#### B. STATEMENT OF GROUNDS

The reference listed drug for the proposed generic drug product is Remeron® Tablets (mirtazapine), 15 mg. The recommended starting dose for REMERON® (mirtazapine) Tablets is 15 mg/day, administered in a single dose, preferably in the evening prior to sleep. In the controlled clinical trials establishing the efficacy of REMERON in the treatment of major depressive disorder, the effective dose range was generally 15-45 mg/day.

For 34% of the patients taking Remeron®, 15 mg is a sufficient dose. See IMS Audit (April 2002) (Attachment A). Within this cohort, 22% take a 1 ½ tablet dose. In fact, the 15 mg version of Remeron® (mirtazapine) tablet is scored, to make it possible for patients to cut the tablet in half. The availability of 7.5 mg mirtazapine tablets will make it easier and more convenient for patients prescribed smaller daily doses of mirtazapine tablets to take their medication. Therefore, petitioner seeks a determination that mirtazapine tablets, 7.5 mg, is suitable for an ANDA, with Remeron® tablets, 15 mg as the reference listed drug (RLD).

The active ingredient of the proposed drug product will be the same as that in Remeron® tablets. Because the proposed drug product is dose proportional and contains the same active and inactive ingredients, it should be bioequivalent to Remeron® Tablets. The proposed drug product is expected to have the same therapeutic effect as Remeron® Tablets when administered to patients under the same conditions of use. In accordance with FDA regulations and policies, the client will request a bioequivalency waiver in its ANDA submission.

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Pursuant to 21 CFR 314.93 (d), a copy of the approved labeling for Remeron ® Tablets is included (Attachment B). A copy of the proposed labeling for a generic 7.5 mg strength of that drug product is also included (Attachment C). No changes to the labeling are necessary other than those necessitated by the different strength and manufacturer. The brand name Remeron ® Tablets will be deleted, and descriptions of the strength and tablet and references to the manufacturer of Remeron ® Tablets will be modified.

**C. ENVIRONMENTAL IMPACT**

Pursuant to 21 CFR 25.31(a), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

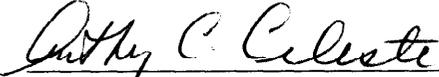
**D. ECONOMIC IMPACT**

According to 21 CFR 10.30 (b), information on economic impact is to be submitted only when requested by the Commissioner following review of this petition.

**E. CERTIFICATION**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

  
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Anthony C. Celeste  
President

Attachments.