ANDA 76-119 January 15, 2002

TEVA Pharmaceuticals USA
Attention: Phillip Erickson
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 26, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Mirtazapine Tablets, 15 mg, 30 mg, and 45 mg.

Reference is also made to your amendments dated April 12, May 2, May 11, May 14, July 27, September 10, November 27, and December 28, 2001.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Remeron Tablets of Organon Inc. (sub. Akzona Inc.), is subject to a period of patent protection which expires on June 16, 2017, [U.S. Patent No. 5,977,099, (the ‘099

patent)]. Your application contains a Paragraph IV Certification to the '099 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. The certification states that the '099 patent is invalid, unenforceable or will not be infringed by your manufacture, use, or sale of this drug product. 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 TEVA Pharmaceuticals USA (TEVA) for infringement of the patent that is the subject of the certification (the '099 patent). You have notified the agency that TEVA has complied with the requirements of Section 505(j)(2)(B) of the Act and that litigation is underway in the United States District Court for the District of New Jersey involving a challenge to the '099 patent (Akzo Nobel N.V. and Organon Inc. v. TEVA Pharmaceuticals USA, Civil Action No. 01-2682 [FSH]). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of a court decision [505(j)(5)(B)(iii) (I), (II), or (III)], or,

   c. the patent has expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

In order to reactivate your application prior to final approval, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED approximately 90 days prior to the date you believe your application may be considered for final approval. Your amendment must provide:

1. A copy of a court order or judgement, a settlement agreement between the parties, a licensing agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

   b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment requesting final approval should be designated as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED

in your cover letter. Should you have additional questions about the status of this application, please contact Mark Anderson, R.Ph., Project Manager, at 301-827-5789.

Sincerely yours,

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