ANDA 75-932

Eon Labs Manufacturing, Inc.
Attention: Sadie M. Ciganek
227-15 North Conduit Avenue
Laurelton, NY 11413

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 26, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Bupropion Hydrochloride Extended-Release Tablets, 100 mg and 150 mg.

Reference is also made to your amendments dated December 11, 2000; October 2, November 13, December 5, 2001; and January 2, and January 18, 2002.

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, Wellbutrin-SR Tablets of Glaxo Wellcome, Inc., is subject to periods of patent protection which expire on August 12, 2013, [U.S. Patent Nos. 5,358,970 (the ‘970 patent), 5,427,798 (the ‘798 patent)), 5,731,000 (the ‘000 patent), 5,763,493 (the ‘493 patent)]; and August 18, 2004, [U.S. Patent No. RE 33,994 (the ‘994 patent)]. Your application contains patent certifications under Section 505 (j)(2)(A)(vii)(IV) of the Act stating that these patents are 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 before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified FDA that Eon Labs Manufacturing, Inc. (Eon) has complied with the requirements of Section 505(j)(2)(B) 0f the Act. As a result, litigation is currently underway in the United States District Court for the Southern District of New York involving a challenge to the '798 and '994 patents (Glaxo Wellcome, Inc. v. Eon Labs Manufacturing, Inc., Civil Action No. 00 Civ 9089). 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 patents have 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 between 60 to 90 days prior to the date you believe your application is eligible for final approval. This amendment should to notify the Agency of the circumstances impacting the final approval date. In addition, Your amendment must provide:

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

2. a. updated information related to final-printed labeling, chemistry, manufacturing and controls data, or any other significant 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 this 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 should be designated as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED in your cover letter. Before you submit the amendment, please contact Stanley Shepperson, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

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