CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-366

APPROVAL LETTER

ANDA 75-366

MAY 1 2000

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

Dear Madam:

This is in reference to your abbreviated new drug application dated April 13, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg and 240 mg.

Reference is also made to our Tentative Approval letters dated July 26, and November 2, 1999, and to your amendments dated February 4, and March 15, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg and 240 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Betapace® Tablets, 80 mg, 120 mg, 160 mg and 240 mg, respectively, of Berlex Laboratories, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the

proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler 5/1/00
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-366 JUL 26 [illegible]

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 dated April 13, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Sotalol Hydrochloride Tablets 80 mg, 120 mg, 160 mg, and 240 mg.

Reference is also made to your amendments dated September 9, 1998; and April 5, April 30, July 19, and July 23, 1999.

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), and is subject to change on the basis of new information that may come to our attention. The listed reference drug product (RLD) upon which you have based your application, Betapace Tablets of Berlex Laboratories, Inc., is subject to a period of Orphan Drug Exclusivity (ODE). Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(D) of the Act until the ODE has expired, i.e., October 30, 1999.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This amendment should be designated

clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the date of final approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

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 product before the final approval date is prohibited under Section 501 of the Act. Also, until the Agency issues the final approval letter, your product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to October 30, 1999, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mr. Mark Anderson, Project Manager, at (301) 827-5849, for further instructions.

Sincerely yours,

D. L. Sporn 7/26/99

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research