DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

ANDA 74-430

FEB 9 1996

Eon Labs Manufacturing, Inc.
Attention: John Purpura
227-15 N. Conduit Avenue
Laurelton, NY 11413

Dear Sir:

This is in reference to your abbreviated new drug application dated December 6, 1993, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Desipramine Hydrochloride Tablets USP, 10 mg and 150 mg.

Reference is also made to your amendments dated October 19, 1995 and November 30, 1995.

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 Desipramine Hydrochloride Tablets USP, 10 mg and 150 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Norpramin® Tablets, 10 mg and 150 mg, respectively, of Merrell Dow Pharmaceuticals, Inc.).

Under 21 CFR 314.70, 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. 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-240). Please do not use Form FD-2253 (

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-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Charles J. Ganley, M.D.

Charles J. Ganley, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research