ANDA 75-280 February 25, 2002

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 December 18, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nabumetone Tablets, 500 mg and 750 mg.

Reference is also made to your Tentative Approval Letter dated August 6, 1998 and your amendments dated April 29, May 8, and June 3, 1998, December 14, and 27, 2001, February 21, and 22, 2002.

The listed drug product referenced in your application (RLD), Relafen® Tablets, 500 mg and 750 mg, of SmithKline Beecham Pharmaceuticals, is subject to a period of patent protection which expires on June 13, 2003 (U.S. Patent No. 4,420,639, the '639 patent). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Nabumetone Tablets, 500 mg and 750 mg, will not infringe on the '639 patent, or that the patent is otherwise invalid. Section 505(j)(5)(B)(III) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Eon Labs Manufacturing, Inc. (Eon) for infringement of the patent that is the subject of the certification. This action must be brought against Eon prior to the expiration of forty-five (45) days from the date the notice, provided by Eon under paragraph (2)(B)(I), is received by the patent and NDA holder. You have notified the Agency that Eon complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, on February 17, 1998, SmithKline Beecham initiated a patent infringement suit on the '639 patent against you in the United States District Court for the District of Massachusetts (SmithKline Beecham Corporation and Beecham Group, p.l.c. v. Eon Labs Manufacturing, Inc., Civil Action No. 98cv10285RCL). With

respect to this litigation, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application has expired.

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 Nabumetone Tablets, 500 mg and 750 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Relafen® Tablets, 500 mg and 750 mg, respectively, of SmithKline Beecham Pharmaceuticals). 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.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete.

We acknowledge your commitment to satisfactorily resolve any deficiencies, which may be identified.

Sincerely yours,

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