



ANDA 74-377

Food and Drug Administration  
Rockville MD 20857

MAY 16 1995

Novopharm  
Attention: Therese M. Ast, Ph.D. (Agent)  
c/o Granutec Inc.,  
4409 Airport Drive N.W.  
Wilson, N.C. 27896

Dear Madam:

This is in reference to your abbreviated new drug application dated June 22, 1993, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Mexiletine Hydrochloride Capsules USP, 150 mg, 200 mg, and 250 mg.

Reference is also made to your amendments dated July 12, 1993, December 15, 1994, January 19, 1995 and March 7, 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 Mexiletine Hydrochloride Capsules USP, 150 mg, 200 mg, and 250 mg, to be bioequivalent and, therefore, therapeutically equivalent to those of the listed drug (Mexitil® Capsules, 150 mg, 200 mg, and 250 mg, respectively, of Boehringer Ingelheim Pharmaceuticals, Inc.). Your dissolution testing should be incorporated into the stability and quality control programs using the same method proposed in your application.

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

Sincerely yours,

A handwritten signature in cursive script, appearing to read "M. Williams", with a long horizontal flourish extending to the right.

Roger L. Williams, M.D.  
Associate Director for Science and Medical Affairs  
Center for Drug Evaluation and Research