CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74467

APPROVAL LETTER

ANDA 74-467

AUG 29 1997

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2655 W. Midway Blvd.
P.O. Box 466
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 16, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Tablets USP, 150 mg and 300 mg (present as the hydrochloride).

Reference is also made to your amendments dated March 13, April 24, August 27, and August 28, 1997.

The listed drug product referenced in your application is subject to a period of patent protection which expires June 4, 2002, (patent 4,521,431). 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 ranitidine hydrochloride will not infringe on the patent or that the patent is otherwise invalid. You further informed the Agency that Glaxo, Inc. initiated a patent infringement suit against you in the United States District Court for the District of New Jersey (Glaxo Inc., Glaxo Group Limited, and Allen & Hanburys Limited v. Geneva Pharmaceuticals Inc., Ciba-Geigy Corporation, Interchem Trading Corporation and Union Quimico Farmaceutica S.A., Civil Action Nos. 94-1921 and 94-4589.) You also have notified the Agency that the case was dismissed with prejudice on August 6, 1997.

The Agency also recognizes that the 30-month period identified in Section 505(j)(4)(B)(iii) of the Act, during which time FDA was precluded from approving your application, expired prior to the August 6, 1997 decision of the court.

The Agency has reviewed the application of the 180-day exclusivity provisions of the Act in reference to the ANDAs submitted for ranitidine hydrochloride tablets, and has concluded that Genpharm, Inc., as the first ANDA applicant to submit a

Paragraph IV Certification to the patent listed for the referenced drug, received the right to the 180-days of exclusivity. This period of exclusivity expires on August 29, 1997.

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 Ranitidine Tablets USP, 150 mg and 300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zantac Tablets, 150 mg and 300 mg, respectively, of Glaxo Wellcome, Inc.). Your dissolution testing should be incorporated into the stability and quality control program 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,

/S/

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