ANDA 76-175 February 20, 2002

Geneva Pharmaceuticals Technology Corporation
Attention: Pankaj Dave, Ph.D.
2400 Route 130 North
Dayton, NJ 08810

Dear Sir:

This is in reference to your abbreviated new drug application dated May 23, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Mefloquine Hydrochloride Tablets, 250 mg.

Reference is also made to your amendments dated June 7, July 2, July 11, July 30, October 12, October 25, October 26, and November 5, 2001.

The listed drug referenced in your application, Lariam Tablets of Hoffmann La Roche, Inc., is subject to a period of patent protection which will expire on October 1, 2004 [U.S. Patent No. 4,579,855 (the '855 patent)]. Your application contains a patent certification to the '855 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use or sale of this drug product will not infringe the patent, or that the claims of the patent are invalid and/or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification (the '855 patnet) before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Geneva Pharmaceuticals Technology Corporation (Geneva) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Geneva within the statutory forty-five day period.

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 Mefloquine Hydrochloride Tablets, 250 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lariam® Tablets, 250 mg, of Hoffmann La Roche, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Geneva Pharmaceuticals Technology Corporation (Geneva) was the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification. Therefore, with this approval Geneva is eligible for 180-days of market exclusivity. Such exclusivity will begin to run either from the date Geneva begins commercial marketing of the drug product, or in the absence of marketing, from the date of a decision of a court finding the '855 patent invalid or not infringed whichever event occurs earlier [Section 505(j)(5)(B)(iv)].

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patent invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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 that 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 that may be identified.

Sincerely yours,

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