

ANDA 65-068

February 26, 2001

Geneva Pharmaceuticals, Inc.  
Attention: Beth Brannan  
U.S. Agent for: Biochemie GmbH  
2555 W. Midway Boulevard  
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application dated March 29, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Penicillin G Sodium for Injection USP, 5,000,000 units/vial. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

This application was granted "Expedited Review Status" pursuant to the office's Manual of Policies and Procedures (MaPP) 5240.1 based upon public health need of a medically necessary drug product.

Reference is also made to your amendments dated August 16, September 25, October 2, November 9, December 4, and December 21, 2000.

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 Penicillin G Sodium for Injection USP, 5,000,000 units/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Penicillin G Sodium for Injection USP, 5,000,000 units/vial, of Marsam Pharmaceuticals, Inc.).

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.

Sincerely yours,

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

