



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 40-268

Food and Drug Administration  
Rockville MD 20857

Trigen Laboratories, Inc.  
Attention: Rajan Embran  
207 Kiley Drive  
Salisbury, MD 21801

FEB 27 1998

**received**  
3/5/98 RE

Dear Sir:

This is in reference to your abbreviated new drug application dated August 5, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Prochlorperazine Maleate Tablets USP, 5 mg (base) and 10 mg (base).

Reference is also made to your amendments dated September 11, October 31, and November 7 and 24, 1997; and January 7 and 29, 1998.

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 Prochlorperazine Maleate Tablets USP, 5 mg (base) and 10 mg (base) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Compazine Tablets, 5 mg (base) and 10 mg (base), 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 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 dark ink, appearing to read "D. L. Sporn". The signature is fluid and cursive, with the first name "D." and last name "Sporn" clearly distinguishable.

Douglas L. Sporn  
Director

Office of Generic Drugs  
Center for Drug Evaluation and Research