

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75313

APPROVAL LETTER

FEB 7 2000

Zenith Goldline Pharmaceuticals, Inc.
Attention: Pat Jaworski
U.S. Agent for: Steripak Limited
140 Legrand Avenue
Northvale, NJ 07647

Dear Sir:

This is in reference to your abbreviated new drug application dated December 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ipratropium Bromide Inhalation Solution, 0.02%, packaged in 0.5 mg/2.5 mL unit-dose vials.

Reference is also made to your amendments dated May 12, and May 13, 1998; and December 14, 1999 and January 13, 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 Ipratropium Bromide Inhalation Solution, 0.02%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Atrovent® Inhalation Solution, 0.02%, of Boehringer Ingelheim 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 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-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,

/S/

Douglas L. Sporn
Director

Office of Generic Drugs
Center for Drug Evaluation and Research

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