CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-111

APPROVAL LETTER

ANDA 75-111

APR 22 1999

Alpharma, U.S. Pharmaceuticals Division
Attention: Ronald Bynum
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Sir:

This is in reference to your abbreviated new drug application dated April 11, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ipratropium Bromide Inhalation Solution, 0.02%.

Reference is also made to your amendment dated March 24, 1999.

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 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 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,

D. L. Sporn 4-22-99

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

cc:

4/9/99

4/4/99

4/7/99