

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-111

ADMINISTRATIVE DOCUMENTS

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS
BIO/STABILITY?

ALPharma's intended production batch sizes is

Manufacturing process is identical to that used for the
exhibit/stability batch.

cc:

Endorsements:

non-graded issue sec 4/9/95
...

**REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH**

ANDA Number: **75-111** Date of Submission: **April 11, 1997**

Applicant's Name: **Alpharma, U.S. Pharmaceuticals Division**

Established Name: **Ipratropium Bromide Inhalation Solution, 0.02%**

Labeling Deficiencies:

1. GENERAL COMMENT

The description of the container closure system on page 508 of this submission, indicates an area available for labeling or engraving on the vial card. Please identify what will be engraved in this area.

2. UNIT DOSE VIAL (2.5 mL)

- a. Place "0.5 mg/2.5 mL" in parentheses.
- b. Include the name and place of business of the manufacturer or distributor.
- c. Revise to read:

FOR ORAL INHALATION ONLY

[Note: Insert "ORAL".]

- d. We encourage the use of the NDC number.

3. UNIT DOSE FOIL POUCH (12 x 2.5 mL)

- a. See comment c under UNIT DOSE VIAL.
- b. Delete the "0.02%" and "(0.5 mg/vial)" that appears in the right hand corner of the label and revise the product strength to read as follows:

0.02%
(0.5 mg/vial)

- c. Revise to read "Usual Dosage" rather than "Dosage".
- d. Revise the storage temperature recommendations to read as follows:

Store at 20° to 25°C (68° to 77°F). Protect...

4. UNIT DOSE CARTON

See comments under UNIT DOSE FOIL POUCH.

5. INSERT

a. PRESCRIBING INFORMATION INSERT

i. DESCRIPTION

Revise the last paragraph to read as follows:

...nebulizer. Each vial contains ipratropium bromide 0.02% (0.5 mg/vial) in a preservative-free isotonic sterile aqueous solution containing sodium chloride. Adjusted to pH...

ii. ADVERSE REACTIONS

Table - Revise the second and third column heading to read "metaproterenol" rather than "Alupent®". In addition, capitalize the "G" in "Body as a Whole-General Disorders".

iii. HOW SUPPLIED

See comment d under UNIT DOSE FOIL POUCH.

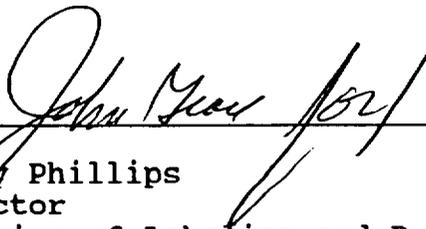
b. PATIENT'S INSTRUCTIONS FOR USE INSERT

See comment d under UNIT DOSE FOIL POUCH.

Please revise your unit dose vial labels, foil pouch, unit dose carton and insert labeling, as instructed above, and submit final printed labels and labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.



Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research