

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75313

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

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| <p>We called Jason Gross of Zenith Goldline, U.S. Agent for Steripak, regarding ANDA 75-313, Ipratropium Bromide Inhalation Solution, 0.02%.</p> <p>Mr. Ken Furnkranz informed the firm that there is one minor deficiency from the analytical methods that were evaluated by the Philadelphia Laboratory: A correction for the water content in the drug substance is necessary in the assay method for the drug substance and the drug product. In addition, a method for the determination of water content of the drug substance should be indicated.</p> <p>Mr. Furnkranz informed the firm that they should respond to the deficiency as a telephone amendment.</p> <p>I informed the firm that the response must be responded to within 10 calendar days.</p> <p>Dr. Gross agreed to respond to the deficiency as a telephone amendment within 10 calendar days.</p> | <p>DATE January 12, 2000</p> |
| | <p>ANDA NUMBER 75-313</p> |
| | <p>IND NUMBER</p> |
| | <p align="center">TELECON</p> |
| | <p>INITIATED BY SPONSOR FDA X</p> |
| | <p>PRODUCT NAME Ipratropium Bromide Inhalation Solution, 0.02%</p> |
| | <p>FIRM NAME Steripak Limited</p> |
| | <p>NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Jason Gross, PharmD.of Zenith Goldline, US Agent for Steripak</p> |
| | <p>TELEPHONE NUMBER (201) 767-1700 Ext. 239</p> |
| | <p>SIGNATURE M. Dillahunt <i>/S/</i> K. Furnkranz <i>/S/</i></p> <p><i>1/12/00</i></p> |

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CC: ANDA 75-313

Chem Div I, T-con Notebook

RECORD OF TELEPHONE CONVERSATION/MEETING

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|--|---|
| <p>Allen Rudman, Michael Smela and myself called Jason Gross to inform him that we did not include 1 deficiency in our major deficiency fax of July 27, 1998. The firm responded on August 24, 1998. The issue of the overwrap requirement and the sensitivity of the methods was not addressed in the review done in Branch 3. We told Mr. Gross to refer to our letters for ANDA 75343 (Albuterol Sulfate Inhalation Solution) and ANDA 75271 (Cromolyn Sodium Inhalation Solution) for the identical deficiency. Gross said he needs a separate letter addressed to this specific ANDA. We told him we would do that.</p> | DATE: October 21, 1998 |
| | ANDA NUMBER: 75313 |
| | IND NUMBER: N/A |
| | TELECON |
| | INITIATED BY: <input type="checkbox"/> APPLICANT/SPONSOR <input checked="" type="checkbox"/> FDA |
| | MADE: <input checked="" type="checkbox"/> BY TELEPHONE <input type="checkbox"/> IN PERSON |
| | PRODUCT NAME: Ipratropium Bromide Inhalation Solution |
| | FIRM NAME: Zenith/Steripak |
| | NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Jason Gross |
| | TELEPHONE NUMBER: |
| SIGNATURE: <div style="text-align: right;"><hr/>Paul Schwartz, Ph.D. Team Leader</div> | |

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

ANDA Number: 75-313

Applicant's Name: Steripak Limited

Date of Submission: October 22, 1999

Established Name: Ipratropium Bromide Inhalation Solution, 0.02% (0.5 mg/2.5 mL)

Labeling Deficiencies:

1. UNIT DOSE CONTAINER (2.5 mL)

- a. Submit a drawing of the unit dose container with all pertinent information typed in where it is to appear on the vial.

2. FOIL POUCH (5 x 2.5 mL)

- a. Revise "Retain in carton until time of use" to read "Retain in foil pouch until time of use".
- b. Revise your "Each mL..." statement to be consistent with your carton labeling which reads as follows:

Each Low Density Polyethylene Vial Contains: 2.5 mL Ipratropium Bromide 0.02% preservative-free, sterile, isotonic aqueous solution containing sodium chloride. Adjusted to pH 3.4 (3 to 4) with hydrochloric acid.

3. CARTON (25 x 2.5 mL and 60 x 2.5 mL)

- a. See comment (a) under FOIL POUCH.

4. PHYSICIAN INSERT

a. CLINICAL PHARMACOLOGY

Revise the first sentence of paragraph three of this section to read as follows:

The bronchodilation following inhalation of ...

b. ADVERSE REACTIONS

Table

Relocate "All Adverse Events from a Double..." to appear as the title of the table above "PERCENT OF PATIENTS".

c. HOW SUPPLIED

- i. See comment (a) under FOIL POUCH.
- ii. Revise your HOW SUPPLIED statement to include reference to the foil pouch and the number of vials per pouch.

5. PATIENT INSTRUCTIONS FOR USE INSERT

- a. Instruction #5 – BOLD the following parts of sentence one:

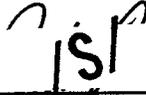
Breathe as calmly, deeply, and evenly...

- b. See comment (a) under FOIL POUCH.

Please revise your unit dose container, foil pouch, carton, physician's insert and patient's instructions for use insert labeling, as instructed above, and submit 12 copies of final print labeling.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes to the reference listed drug. We suggest that you routinely monitor the following website for any approved changes: http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

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.



Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research