CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75313

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS
HFD-620
Microbiology Review #1
May 11, 1999

A. 1. **ANDA:** 75-313

APPLICANT: Zenith Goldline Pharmaceuticals
140 Legrand Ave.
Northvale, NJ 07647

US Authorized Agent for:
Steripak Limited
Goddard Road
Astmoor, Runcorn
Chesire WA7IQF
England

2. PRODUCT NAME: Ipratropium Bromide Inhalation Solution, 0.02%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution, 0.5 mg/2.5 mL, single-dose vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anticholinergic bronchodilator

B. 1. DATE OF INITIAL SUBMISSION: Dec. 30, 1997
Subject of this Review (Received Jan. 6, 1998)

2. DATE OF AMENDMENTS: 8/24/98
5/13/98

3. RELATED DOCUMENTS:
ANDA 75-343
ANDA 75-271
NDA
DMF

4. ASSIGNED FOR REVIEW: April 26,1999

C. REMARKS: The Applicant has informed the Agency (10/9/98 letter) that the ANDAs 75-313, 75-343 and 75-271 are manufactured at the same facility (Steripak, Chesire, UK), employing the same equipment and similar processes. Also, the Applicant states that the same microbiological information package was provided in each of these applications.

The product is manufactured by Steripak

Limited, Goddard Road, Astmoor, Runcorn, Chesire, England WA7IQF.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the are provided in "E. Review Notes" and a Microbiologist's draft of deficiencies to be provided to the Applicant found at the end of the review.

/S/ 5/12/99
Lynne A. Ensor, Ph. D.

cc: Original **ANDA 75-313**
Duplicate ANDA
Division Copy
Field Copy
Drafted by L. Ensor, HFD 620 x:wp\microrev\75313
Initialed by M. Fanning, P. Cooney 5/27/99

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Micro-Review #1

Microbiology Comments to be Provided to the Applicant

ANDA: 75-313 APPLICANT: Zenith Goldline (Steripak)

DRUG PRODUCT: Ipratropium Bromide Inhalation Solution, 0.02%

A. Microbiology Deficiencies:

Please clearly identify your amendment to this facsimile as "RESPONSE TO MICROBIOLOGY DEFICIENCIES". The "RESPONSE TO MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,

/S/

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS
HFD-620
Microbiology Review #2
November 8, 1999

A. 1. **ANDA:** 75-313

APPLICANT: Zenith Goldline Pharmaceuticals
140 Legrand Ave.
Northvale, NJ 07647

US Authorized Agent for:
Steripak Limited
Goddard Road
Astmoor, Runcorn
Chesire WA7IQF
England

2. PRODUCT NAME: Ipratropium Bromide Inhalation Solution, 0.02%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution, 0.5 mg/2.5 mL, single-dose vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anticholinergic bronchodilator

B. 1. DATE OF INITIAL SUBMISSION: Dec. 30, 1997
(Received Jan. 6, 1998)

2. DATE OF AMENDMENTS: July 15,1999
Subject of this Review (Received July 16, 1999)

3. RELATED DOCUMENTS: N/A

4. ASSIGNED FOR REVIEW: November 8,1999

C. REMARKS: The subject amendment provides a response to the Microbiology Deficiencies communicated to the applicant in the June 3, 1999 letter.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the are provided in "E. Review Notes" and a Microbiologist's draft of deficiencies to be provided to the Applicant found at the end of the review.

/S/ 11/8/99
Lynne A. Ensor, Ph. D.

CSH 11/10/99
MZ. 11/12/99

cc: Original **ANDA** 75-313
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Micro Review #2

OFFICE OF GENERIC DRUGS
HFD-620
Microbiology Review #3
January 5, 2000

A. 1. **ANDA:** 75-313

APPLICANT: Zenith Goldline Pharmaceuticals
140 Legrand Ave.
Northvale, NJ 07647

US Authorized Agent for:
Steripak Limited
Goddard Road
Astmoor, Runcorn
Chesire WA7IQF
England

2. PRODUCT NAME: Ipratropium Bromide Inhalation Solution, 0.02%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution, 0.5 mg/2.5 mL, single-dose vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anticholinergic bronchodilator

B. 1. DATE OF INITIAL SUBMISSION: Dec. 30, 1997
(Received Jan. 6, 1998)

2. DATE OF AMENDMENTS: July 15,1999
(Received July 16, 1999)

December 14,1999
Subject of this Review (Received December 15, 1999)

3. RELATED DOCUMENTS: N/A

4. ASSIGNED FOR REVIEW: January 4, 2000

C. REMARKS: The subject amendment provides a response to the Microbiology Deficiencies communicated to the applicant in the December 10, 1999 letter.

D. CONCLUSIONS: The submission **is recommended** for approval on the basis of sterility assurance. Specific comments regarding the are provided in "E. Review Notes".

/S/ 1/5/00

Lynne A. Ensor, Ph. D.

cc: Original **ANDA** 75-313
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Micro Review #3