

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-271

MICROBIOLOGY REVIEW

REVIEW FOR OFFICE OF GENERIC DRUGS
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF ANDA 75-271
21 December 1999

A. 1. ANDA 75-271

APPLICANT: Zenith Goldline Pharmaceuticals
140 Legrand Avenue
Northvale, NJ 07647

US Authorized Agent for:

Steripak Limited
Goddard Road
Astmoor, Runcorn
Cheshire WA71QF
England

2. PRODUCT NAME: Cromolyn Sodium Inhalation Solution 1%, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product indicated in the management of patients with bronchial
asthma.

4. METHODS OF STERILIZATION:
The product is technology

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The product is an inhalation solution.

B. 1. DATE OF INITIAL SUBMISSION: 9 October 1998

2. DATE OF AMENDMENT: 29 July 1999 (Subject of this Review)

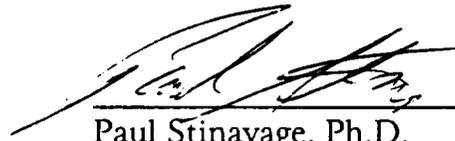
3. RELATED DOCUMENTS: ANDA 75-313, ANDA 75-343

4. ASSIGNED FOR REVIEW: 27 October 1999

C. REMARKS: This application was received for consultative review from
the Office of Generic Drugs.

The product is manufactured by Steripak Limited,
Goddard Road, Astmoor, Runcorn, Chesire, England
WA71QF. The product is packaged in 3.5 mL
container with a fill volume of ... mL.

D. CONCLUSIONS: The application is recommended for approval on
the basis of sterility assurance.


Paul Stinavage, Ph.D. 21 December 1999
D/C 12/22/99

CC:

Drafted by: P. Stinavage, 21 December 1999
R/D initialed by P. Cooney

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Information and are not

releasable.

Micro Rev 2

12/21/99

REVIEW FOR OFFICE OF GENERIC DRUGS
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF ANDA 75-271
11 April 1999

APR 12 1999

A. 1. ANDA 75-271

APPLICANT: Zenith Goldline Pharmaceuticals
140 Legrand Avenue
Northvale, NJ 07647

US Authorized Agent for:

Steripak Limited
Goddard Road
Astmoor, Runcorn
Cheshire WA71QF
England

2. PRODUCT NAME: Cromolyn Sodium Inhalation Solution 1%, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product indicated in the management of patients with bronchial asthma.

4. METHODS OF STERILIZATION:
The product is _____ 1 technology

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is an inhalation solution.

B. 1. DATE OF INITIAL SUBMISSION:

~~9 October 1998~~

~~27 August 1998~~

12/15/97

[Signature] 4/14/99

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: ANDA 75-313, ANDA 75-343

4. ASSIGNED FOR REVIEW: 7 April 1999

C. REMARKS: This application was received for consultative review from the Office of Generic Drugs.

The product is manufactured by Steripak Limited,
Goddard Road, Astmoor, Runcorn, Chesire, England
WA71QF. The product is packaged in 3.5 mL
blow/fill/seal container with a fill volume of 2.0 – 2.2 mL.

D. CONCLUSIONS: The application is approvable upon resolution of microbiology concerns. Specific comments are provided in "E. Review Notes" and "List of Microbiology Deficiencies".


Paul Stinavage, Ph.D. 11 April 1999

PAC 4/12/99

CC:

Drafted by: P. Stinavage, 11 April 1999
R/D initialed by P. Cooney

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Micro Rev.

4/11/99