# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**75-271**

## CHEMISTRY REVIEW(S)

Chemistry Closed

1. **CHEMIST's REVIEW #4**

2. **ANDA 75-271**

3. **APPLICANT, Name/Address/Telephone/Fax:**
Zenith Goldline Pharmaceuticals
Attention: Jason A. Gross
140 Legrand Avenue
Northvale, NJ 07647
Tel# (210) 767-1700. FAX# (800) 631-1583

US authorized agent for:
Steripak Limited, UK
(wholly owned subsidiaries of *IVAX Corp*)

4. **LEGAL BASIS FOR ANDA SUBMISSION:** *505(j)*

5. **SUPPLEMENT:** n/a

6. **PROPRIETARY NAME:** none

7. **Non-PROPRIETARY NAME:** Cromolyn Sodium Inhalation Solution USP, 1.0%
Innovator's Product Name: Intal® Nebulizer Solution; Rhone Poulenc Rorer (formerly Fisons Ltd.

8. **Supplement Provides For:** n/a

9. **AMENDMENTS & OTHER DATES.**

**FIRM:**

| | |
|---|---|
| 12-11-97 | original submission |
| 01-08-98 | New Correspondence (filing issues) |
| 08-26-98 | ANDA Amendment; Chemistry |
| 10-09-98 | new correspondence (micro issues). |
| 12-30-98 | labeling amendment |
| 03-09-99 | New Correspondence; Request for meeting. |
| 04-12-99 | New Correspondence; Minutes of meeting. |
| 06-24-99 | ANDA Amendment; Chemistry |
| 07-29-99 | Micro Amendment |
| 11-15-99 | Gratuitous Chemistry Amendment |
| 12-01-99 | ANDA FAX Amendment; Chemistry |

**FDA:**

| | |
|---|---|
| 01-20-98 | Receipt of ANDA |
| 02-18-98 | Labeling Review (N/A) |
| 04-02-98 | Per DBE, bioeq. acceptable |
| 07-01-98 | N/A MAJOR Amendment/CR #1 |
| 03-03-99 | Labeling Review (N/A) |

03-08-99 N/A MAJOR Amendment/CR #2
07-15-99 Micro Review #1 (deficient).
11-22-99 Chemistry NA #3 (FAX Amendment request)

**OTHER:**
01-20-98 EER submitted
04-12-98 Micro Review (ONDC); N/A
04-12-99 N/A (micro issues)
07-15-99 Method Verification; LA District Lab; Adequate.
11-12-99 EER Acceptable for listed firms.

10. **PHARMACOLOGICAL CATEGORY:** Prophylactic agent indicated in the management of patients with bronchial asthma.

11. **Rx or OTC:** **$R_x$**

12. **RELATED ANDA's:** n/a

13. **DOSAGE Form:** solution

14. **POTENCY:** **20 mg/2 mL**

15. **CHEMICAL Name:** see USP 23

16. **Records & Reports:** n/a

17. **COMMENTS.**

**A. General Comments:**

1. The drug substance and drug product are USP items.
2. The Bio review is acceptable 04-02-98.
3. The 7/29/99 Micro Amendment will need to be reviewed.

**B. Comments to the Applicant's Amendment**

1. Steripak has demonstrated that the laminated foil pouch adequately protects, and does not itself contaminate the drug product.

18. **CONCLUSIONS & RECOMMENDATIONS:** Chemistry Closed. Pending micro review and submission of FPL.

19. Reviewer/Branch Chief:

Kenneth J. Furnkranz
OGD/DC-1/Br-2

Date Started: 12/9/99

M Smela 12/15/99

Michael J. Smela, Jr.
OGD/DC-1/Br-2; T/L

Labeling amendment of 12/17/99 is acceptable per TW 12/22/99. Micro is acceptable per Steinvage on 12/21/99. ANDA may be approved.

M Smela 1/5/00

Date Completed: 12/13/99

Page(s) 9

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chem Rev 4

12/13/99

1. **CHEMIST's REVIEW #3**

2. **ANDA 75-271**

3. **APPLICANT, Name/Address/Telephone/Fax:**
Zenith Goldline Pharmaceuticals
Attention: Jason A. Gross
140 Legrand Avenue
Northvale, NJ 07647
Tel# (210) 767-1700. FAX# (800) 631-1583

US authorized agent for:
Steripak Limited, UK
(wholly owned subsidiaries of *IVAX Corp*)

4. **LEGAL BASIS FOR ANDA SUBMISSION:** *505(j)*

5. **SUPPLEMENT:** n/a

6. **PROPRIETARY NAME:** none

7. **Non-PROPRIETARY NAME:** Cromolyn Sodium Inhalation Solution USP, 1.0%

Innovator's Product Name: Intal® Nebulizer Solution; Rhone Poulenc Rorer (formerly Fisons Ltd.

8. **Supplement Provides For:** n/a

9. **AMENDMENTS & OTHER DATES.**

A. **FIRM:**

| | |
|---|---|
| 12-11-97 | original submission |
| 01-08-98 | New Correspondence (filing issues) |
| 08-26-98 | ANDA Amendment; Chemistry |
| 10-09-98 | new correspondence (micro issues). |
| 12-30-98 | labeling amendment |
| 03-09-99 | New Correspondence; Request for meeting. |
| 04-12-99 | New Correspondence; Minutes of meeting. |
| 06-24-99 | ANDA Amendment; Chemistry |
| 07-29-99 | Micro Amendment |

B. **FDA:**

| | |
|---|---|
| 01-20-98 | Receipt of ANDA |
| 02-18-98 | Labeling Review (N/A) |
| 04-02-98 | Per DBE, bioeq. acceptable |
| 07-01-98 | N/A MAJOR Amendment/CR #1 |
| 03-03-99 | Labeling Review (N/A) |
| 03-08-99 | N/A MAJOR Amendment/CR #2 |

07-15-99 Micro Review #1 (deficient).

**OTHER:**
01-20-98 EER submitted
04-12-98 Micro Review (ONDC); N/A
04-12-99 N/A (micro issues)
07-15-99 Method Verification; LA District Lab; Adequate.

10. **PHARMACOLOGICAL CATEGORY:** Prophylactic agent indicated in the management of patients with bronchial asthma.

11. **Rx or OTC:** $R_x$

12. **RELATED ANDA's:** n/a

13. **DOSAGE Form:** solution
14. **POTENCY:** **20 mg/2 mL**

15. **CHEMICAL Name:** see USP 23

16. **Records & Reports:** n/a

17. **COMMENTS.**

**A. General Comments:**

1. The drug substance and drug product are USP items.
2. The drug product is a sterile aqueous solution.
3. The Bio review is acceptable 04-02-98.
4. Micro review has not yet been completed for this sterile solution.
5. Unipak inspection necessary.

**B. Comments to the Applicant's Amendment**

1. Steripak must demonstrate that the laminated foil pouch protects, but does not contaminate the drug product.

18. **CONCLUSIONS & RECOMMENDATIONS:** N/A

19. Reviewer/Branch Chief:

Kenneth J. Furnkranz
OGD/DC-1/Br-2

Michael J. Smela, Jr.
OGD/DC-1/Br-2; T/L

Date Started: 10/25/99
Date Completed: 11/5/99
Date Revised: 11/15/99

Page(s) 10

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chem Rev 3

11/5/99