CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA061212Orig1s008

Name: Bacitracin (Ointment;Opthalmic), 500 Units/GM

Sponsor: Padagis US

Approval Date: October 27, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s008

CONTENTS

Reviews / Information Included in this Review

Approval Letter	**X**
Tentative Approval Letter	
Labeling	
Labeling Review(s)	
Proprietary Name Review(s)	
Medical Review(s)	
Chemistry Review(s)	
Bio Pharm/Tox Review	
Bioequivalence Review(s)	
Statistical Review(s)	
Microbiology Review(s)	**X**
Other Review(s)	
Administrative & Correspondence Documents	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s008

APPROVAL LETTER

AADA 60-764/S-010
61-212/S-008
62-166/S-013
62-447/S-014
62-938/S-003
ANDA 80-029/S-035

OCT 27 1995

E. Fougera & Co.
Division of Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

Dear Madam:

This is in reference to your supplemental new drug and antibiotic drug applications dated June 13, 1995, submitted pursuant to 21 CFR 314.70, regarding your abbreviated applications for the following drug products:

AADA 60-764	Neomycin & Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP
AADA 61-212	Bacitracin Ophthalmic Ointment USP
AADA 62-166	Neomycin & Polymyxin B Sulfates and Bacitracin Zinc with Hydrocortisone Acetate Ophthalmic Ointment USP
AADA 62-447	Erythromycin Ophthalmic Ointment USP
AADA 62-938	Neomycin & Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment USP
ANDA 80-029	Sulfacetamide Ophthalmic Ointment USP

Reference is also made to your amendments dated September 7, 1995.

The supplemental applications provide for the relocation of the [redacted] (b) (4)

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug/antibiotic application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

10/27/95

Frank O. Holcombe, Jr., Ph.D.
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: AADA 60-764/S-010
61-212/S-008
62-166/S-013
62-447/S-014
62-938/S-003
ANDA 80-029/S-035
Division File (6)
HFD-600/RF
FIELD COPY

Endorsements:
HFD-617/M.Anderson/9/21/95 Mark Anderson 10/25/95
HFD-620/K.Muhvich/9/26/95 K.H.Muhvich 10/26/95
HFD-643/J.Harrison/9/26/95 J.Harrison 10/26/95
HFD-629/P.Schwartz/9/26/95 P.S. 10/26/95
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F/T by pah/10/25/95
APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s008

MICROBIOLOGY REVIEW(s)

A5.1

DIVISION OF CHEMISTRY I
OFFICE OF GENERIC DRUGS

Microbiologist's Review #2

September 14, 1995

A. 1. ANDA: **80-029/S-035 Multiple Supplements - Expedited Review**

APPLICANT: E. Fougera & Co.
Division of Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, N.Y. 11747

2. PRODUCT NAME: **Sulfacetamide Sodium Ophthalmic Ointment USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10% sterile ophthalmic ointment for topical administration

4. METHOD(S) OF STERILIZATION: (b) (4)

5. PRINCIPLE INDICATIONS: For treatment of conjunctivitis and other superficial ocular infections due to susceptible microorganisms.

6. PHARMACOLOGICAL CATEGORY: Anti-infective sulfonamide

B. 1. DATE OF INITIAL SUBMISSIONS: **June 13, 1995 (Received by OGD on 6/14/95)**

2. DATE OF AMENDMENT:

September 7, 1995 (Received by OGD on 9/8/95) - Subject of this Review Sent in response to the Office's letter dated August 23, 1995

3. RELATED SUPPLEMENTS:

AADA 60-764/S-010 Neomycin & Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

AADA 61-212/S-008 Bacitracin Ophthalmic Ointment USP

AADA 62-166/S-013 Neomycin & Polymyxin B Sulfates and Bacitracin Zinc with Hydrocortisone Acetate Ophthalmic Ointment USP

AADA 62-447/S-014 Erythromycin Ophthalmic Ointment USP

AADA 62-938/S-003 Neomycin & Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment USP

4. ASSIGNED FOR REVIEW: September 13, 1995

C. REMARKS: The supplements listed above were submitted under 21 CFR 314.70(c) "Special Supplements - Changes Being Effected." However, the Office denied SSCBE status for these supplements on June 27, 1995, because the new facility had received a prior FDA Form 483 (b) (4) (b) (4) (b) (4) The supplements provided validation data to support (b) (4) of the packaging components at the (b) (4). The information supplied in the submissions was sufficient to determine that the applicant is taking the necessary steps to ensure the sterility of the subject drug products (see above).

D. CONCLUSIONS: The supplements are therefore recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of the Letter to the Applicant".

Kenneth H. Muhvich 9/14/95

Kenneth H. Muhvich, Ph.D.

HFD-620 initialed by RPatel
drafted by: KHMuhvich, 9/14/95 RPatel 9/15/95

cc:

Original **ANDA's 60-764/S-010, 61-212/S-008, 62-166/S-013, 62-447/S-014, 62-938/S-003, 80-029/S-035**

Field Copy

E. REVIEW NOTES:

The OGD Microbiologist's first review of the sterilization process for the subject drug product resulted in two (2) questions, which were communicated via letter to the applicant. Each of the Agency's questions is bolded and followed by a summary of the applicant's response.

1. Provide presterilization bioburden specifications, i.e., alert and action limits, for the (b) (4) to be used for the subject drug product.

(b) (4)

SATISFACTORY

2. Results of a microbial challenge package integrity test should be submitted for the (b) (4) used to prevent contamination of the 1/8 oz (b) (4) ophthalmic ointment tubes.

(b) (4)

SATISFACTORY

DIVISION OF CHEMISTRY I
OFFICE OF GENERIC DRUGS

Microbiologist's Review #1

August 11, 1995

A. 1. ANDA: **80-029/S-035 Multiple Supplements - Expedited Review**

APPLICANT: E. Fougera & Co.
Division of Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, N.Y. 11747

2. PRODUCT NAME: **Sulfacetamide Sodium Ophthalmic Ointment USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10% sterile ophthalmic ointment for topical administration

4. METHOD(S) OF STERILIZATION: (b) (4)

5. PRINCIPLE INDICATIONS: For treatment of conjunctivitis and other superficial ocular infections due to susceptible microorganisms.

6. PHARMACOLOGICAL CATEGORY: Anti-infective sulfonamide

B. 1. DATE OF INITIAL SUBMISSIONS:

June 13, 1995 (Received by OGD on 6/14/95) - Subject of this Review

2. DATE OF AMENDMENT: N/A; no amendment containing sterility assurance information was submitted by the time of this review

3. RELATED SUPPLEMENTS:

AADA 60-764/S-010 Neomycin & Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP

AADA 61-212/S-008 Bacitracin Ophthalmic Ointment USP

AADA 62-166/S-013 Neomycin & Polymyxin B Sulfates and Bacitracin Zinc with Hydrocortisone Acetate Ophthalmic Ointment USP

AADA 62-447/S-014 Erythromycin Ophthalmic Ointment USP

AADA 62-938/S-003 Neomycin & Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment USP

4. ASSIGNED FOR REVIEW: August 10, 1995

C. REMARKS: The supplements listed above were submitted under 21 CFR 314.70(c) "Special Supplements - Changes Being Effected." However, the Office denied SSCBE status for these supplements on June 27, 1995, because the new facility had received a prior FDA Form 483. [redacted] The supplements provided validation data to support [redacted] of the packaging components at the [redacted]. However, the information supplied in the submissions was not sufficient to determine if the applicant is taking the necessary steps to ensure the sterility of the subject drug products (see above). For example, presterilization bioburden specifications, i.e., alert and action limits, for the [redacted] to be used for the subject drug products were not provided.

D. CONCLUSIONS: The supplements are therefore not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of the Letter to the Applicant".

Kenneth H. Muhvich 8/11/95

Kenneth H. Muhvich, Ph.D.

HFD-620 initialed by RPatel
drafted by: KHMuhvich, 8/11/95

RPatel 8/14/95

cc:

Original **ANDA's 60-764/S-010, 61-212/S-008, 62-166/S-013, 62-447/S-014, 62-938/S-003, 80-029/S-035**

Field Copy

4 Pages have been withheld in full as b4 (CCI/TS) immediately following this page

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s008

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

AADA 61-212/S-008
62-166/S-013
62-447/S-014
60-764/S-010
62-938/S-003
ANDA 80-029/S-035

E. Fougera & Co.
division of Altana, Inc.
Attention: Virginia Carman
60 Baylis Road
Melville NY 11747

JUL 5 1995

Dear Madam:

This is in reference to your supplemental antibiotic and new drug applications dated June 13, 1995, submitted pursuant to 21 CFR 314.70(c) regarding the abbreviated applications for:

AADA 61-212	Bacitracin Ophthalmic Ointment USP - Altana
62-166	Neomycin and Polymyxin B Sulfates and Bacitracin Zinc with Hydrocortisone Acetate Ophthalmic Ointment USP - E. Fougera & Co.
62-447	Erythromycin Ophthalmic Ointment USP - E. Fougera Co.
60-764	Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment USP - E. Fougera & Co.
62-938	Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment USP - E. Fougera & Co.
ANDA 80-029	Sulfacetamide Sodium Ophthalmic Ointment USP- Altana Inc.)

You noted that these supplements were being submitted as a "Special Supplement-Changes Being Effected".

The supplemental applications provide for a change in the

(b) (4)

The change that you have described is <u>not</u>, in our opinion, the kind permitted by regulation to be put in effect in advance of approval of a supplement. Rather this change properly fits under 21 CFR 314.70(b)(2)(vi).

This letter is to notify you that approved supplements are required for the proposed change. You were informed of this determination during a June 27, 1995 telephone conversation with Mr. Mark Anderson of this Administration. Please do not implement the proposed change.

Sincerely yours,

John D. Harrison 7/5/95

for Florence S. Fang
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

CC:
AADA 60-764/S-010
61-212/S-008
62-166/S-013
62-447/S-014
62-938/S-003
ANDA 80-029/S-035
DUP/Division Files (6)
HFD-600/RF
FIELD COPY
Endorsements:
HFD-617/M.Anderson/7/3/95 Mark Anderson 7/3/95
HFD-643/S.Rosencrance for JHarrison/6/28/95 S Rosencrance for J Harrison 7/6
X:60-764SP.SUP
B:
F/T by: ol/7/3/95
SPECIAL SUPPLEMENT DENIED