

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA061212Orig1s009

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

Sponsor: Padagis US

Approval Date: March 07, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s009
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)	X
Bio Pharm/Tox Review	
Bioequivalence Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Other Review(s)	
Administrative & Correspondence Documents	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s009

APPROVAL LETTER

61212
S9
V5.1

AADA/ANDA See Attached List

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

MAR 7 1996

Dear Madam:

This is in reference to your 37 supplemental new drug applications dated December 13, 1995, submitted pursuant to 21 CFR 314.70, regarding your abbreviated new drug applications listed on the attachment to this letter.


The supplemental applications provide for [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 application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

 3/7/96

S. Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment

AADA/ANDA

18-861/S-007	Betamethasone Valerate Cream USP, 0.1%
18-865/S-010	Betamethasone Valerate Ointment USP, 0.1%
19-137/S-011	Betamethasone Dipropionate Cream USP, 0.05%
19-141/S-014	Betamethasone Dipropionate Ointment USP, 0.05%
80-029/S-037	Sulfacetamide Sodium Ophthalmic Ointment USP, 10%
18-862/S-008	Betamethasone Valerate Cream USP, 0.1%
18-863/S-009	Betamethasone Valerate Ointment USP, 0.1%
19-138/S-011	Betamethasone Dipropionate Cream USP, 0.05%
19-143/S-013	Betamethasone Dipropionate Ointment USP, 0.05%
87-887/S-015	Triple Sulfa Vaginal Cream USP
89-414/S-005	Hydrocortisone Cream USP, 2.5%
72-933/S-001	Fluocinonide Gel USP, 0.05%
73-030/S-001	Fluocinonide Cream USP, 0.05%
80-692/S-026	Hydrocortisone Ointment USP, 1%
80-693/S-051	Hydrocortisone Cream USP, 1%
81-203/S-006	Hydrocortisone Ointment USP, 2.5%
85-691/S-033	Triamcinolone Acetonide Ointment USP, 0.1% & 0.025%
85-692/S-051	Triamcinolone Acetonide Cream USP, 0.1% and 0.025%
86-424/S-029	Triple Sulfa Vaginal Cream USP
88-168/S-005	Fluocinolone Acetonide Ointment USP, 0.025%
88-169/S-004	Fluocinolone Acetonide Cream USP, 0.025%
88-170/S-005	Fluocinolone Acetonide Cream USP, 0.01%
62-166/S-015	Neomycin/Polymyxin B Sulfates, Bacitracin Zinc/Hydrocortisone Acetate Ophthalmic Ointment USP
62-938/S-005	Neomycin/Polymyxin B Sulfates/Dexamethasone Ophthalmic Ointment USP
62-531/S-006	Gentamicin Sulfate Cream USP, 0.1%
62-533/S-004	Gentamicin Sulfate Ointment USP, 0.1%
60-764/S-011	Neomycin/Polymyxin B Sulfates/Bacitracin Zinc Ophthalmic Ointment USP
61-212/S-009	Bacitracin Zinc Ophthalmic Ointment USP
62-124/S-006	Nystatin Ointment USP 100,000 u/g
62-129/S-002	Nystatin Cream USP 100,000 u/g
62-597/S-003	Nystatin/Triamcinolone Acetonide Cream USP, 100,000 units/mg
62-601/S-002	Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 units/mg
62-599/S-014	Nystatin/Triamcinolone Acetonide Cream USP, 100,000 units/mg
62-602/S-003	Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 units/mg
62-447/S-018	Erythromycin Ophthalmic Ointment USP, 5 mg/g
80-198/S-020	Lidocaine Ointment USP, 5%
87-355/S-016	Nitroglycerin Ointment USP 2%

cc: ANDA #See Attachment
ANDA #See Attachment/Division File
Field Copy
HFD-600/Reading File
HFD-82

Endorsements:

HFD-627/N.Nashed/2-22-96
HFD-627/P.Schwartz, Ph.D./3-4-96
HFD-617/AMWeikel, CSO/3-5-96
X:\WPFILE\MAJORS\NASHED\ALTANA.GL
F/T by MM 3-6-96
Approval Letter

NW 3/6/96
PS 3/6/96

MMW
3/6/96

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s009

CHEMISTRY REVIEW(s)

- 1. CHEMISTRY REVIEW NO. 1
- 2. ANDA # See Attached list
- 3. NAME AND ADDRESS OF APPLICANT

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

4. LEGAL BASIS FOR SUBMISSION

N/A

5. SUPPLEMENT(s)

12/13/95

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

See attached list

8. SUPPLEMENT(s) PROVIDE(s) FOR:

[REDACTED] (b) (4)

9. AMENDMENTS AND OTHER DATES:

N/A

10. PHARMACOLOGICAL CATEGORY

See attached list

11. Rx or OTC

12. RELATED IND/NDA/DMF(s)

DMF's (b) (4)

13. DOSAGE FORM

See attached list

14. POTENCY

See attached list

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS

17. COMMENTS

The Supplements have granted Expedited Review on 1/6/96.

18. CONCLUSIONS AND RECOMMENDATIONS

The Supplements are approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

2/22/96

Supervisor: Paul Schwartz, Ph.D.

2/22/96

20. COMPONENTS AND COMPOSITION

N/A

21. FACILITIES AND PERSONNEL

N/A

22. SYNTHESIS

N/A

23. RAW MATERIAL CONTROLS

N/A

24. OTHER FIRM(s)

N/A

25. MANUFACTURING AND PROCESSING

N/A

26. CONTAINER

(b) (4)

27. PACKAGING AND LABELING

N/A

28. LABORATORY CONTROLS (IN-PROCESS AND FINISHED DOSAGE FORM)

N/A

29. STABILITY

The reviews for stability data done by Norman Gregory, Vernon Walton, D. James, and Susan Rosencrance indicate that the stability data are acceptable.

30. CONTROL NUMBERS

31. SAMPLES AND RESULTS

N/A

32. LABELING

N/A

33. ESTABLISHMENT INSPECTION

N/A

34. BIOEQUIVALENCY STATUS

N/A

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:

N/A

36. ORDER OF REVIEW:

The application submission(s) covered by this review was
taken in the date order of receipt Yes _____
No XXXXX_____

If no, explain reason(s) below:

The Supplements are Expedited.

cc: ANDA #See Attachment
ANDA #See Attachment/Division File
Field Copy

Endorsements:

HFD-627/N.Nashed/2-22-96 *NW 3/6/96*

HFD-627/P.Schwartz, Ph.D./2-22-96 *PS 3/6/96*

X:\WPFILE\MAJORS\NASHED\ALTANA.GOB
F/T MM 3-6-96
Approval Letter

37. DMF CHECKLIST FOR ANDA/AADA # REVIEW # _____

<u>DMF #</u>	<u>DMF TYPE/SUBJECT/HOLDER</u>	<u>ACTION CODE</u>	<u>RESULT OF REVIEW</u>	<u>DATE REVIEW COMPLETED</u>
--------------	--------------------------------	--------------------	-------------------------	------------------------------

(b)(4)

4

4

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;	(3) Reviewed previously and no revision since last review;
(4) Sufficient information in application;	(5) Authority to reference not granted;
(6) DMF not available;	(7) Other (explain under "Comments").

Page 1 of 1 . N.Nashed

Reviewer

N. Nashed 3/6/96 2/22/96

Signature Date

AADA/ANDA

18-861/S-007	Betamethasone Valerate Cream USP, 0.1%
18-865/S-010	Betamethasone Valerate Ointment USP, 0.1%
19-137/S-011	Betamethasone Dipropionate Cream USP, 0.05%
19-141/S-014	Betamethasone Dipropionate Ointment USP, 0.05%
80-029/S-037	Sulfacetamide Sodium Ophthalmic Ointment USP, 10%
18-862/S-008	Betamethasone Valerate Cream USP, 0.1%
18-863/S-009	Betamethasone Valerate Ointment USP, 0.1%
19-138/S-011	Betamethasone Dipropionate Cream USP, 0.05%
19-143/S-013	Betamethasone Dipropionate Ointment USP, 0.05%
87-887/S-015	Triple Sulfa Vaginal Cream USP
89-414/S-005	Hydrocortisone Cream USP, 2.5%
72-933/S-001	Fluocinonide Gel USP, 0.05%
73-030/S-001	Fluocinonide Cream USP, 0.05%
80-692/S-026	Hydrocortisone Ointment USP, 1%
80-693/S-051	Hydrocortisone Cream USP, 1%
81-203/S-006	Hydrocortisone Ointment USP, 2.5%
85-691/S-033	Triamcinolone Acetonide Ointment USP, 0.1% & 0.025%
85-692/S-051	Triamcinolone Acetonide Cream USP, 0.1% and 0.025%
86-424/S-029	Triple Sulfa Vaginal Cream USP
88-168/S-005	Fluocinolone Acetonide Ointment USP, 0.025%
88-169/S-004	Fluocinolone Acetonide Cream USP, 0.025%
88-170/S-005	Fluocinolone Acetonide Cream USP, 0.01%
62-166/S-015	Neomycin/Polymyxin B Sulfates, Bacitracin Zinc/Hydrocortisone Acetate Ophthalmic Ointment USP
62-938/S-005	Neomycin/Polymyxin B Sulfates/Dexamethasone Ophthalmic Ointment USP
62-531/S-006	Gentamicin Sulfate Cream USP, 0.1%
62-533/S-004	Gentamicin Sulfate Ointment USP, 0.1%
60-764/S-011	Neomycin/Polymyxin B Sulfates/Bacitracin Zinc Ophthalmic Ointment USP
61-212/S-009	Bacitracin Zinc Ophthalmic Ointment USP
62-124/S-006	Nystatin Ointment USP 100,000 u/g
62-129/S-002	Nystatin Cream USP 100,000 u/g
62-597/S-003	Nystatin/Triamcinolone Acetonide Cream USP, 100,000 units/mg
62-601/S-002	Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 units/mg
62-599/S-014	Nystatin/Triamcinolone Acetonide Cream USP, 100,000 units/mg
62-602/S-003	Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 units/mg
62-447/S-018	Erythromycin Ophthalmic Ointment USP, 5 mg/g
80-198/S-020	Lidocaine Ointment USP, 5%
87-355/S-016	Nitroglycerin Ointment USP 2%

H 6/2/92

OFFICE OF GENERIC DRUGS

EXPEDITED REVIEW REQUESTED

ANDA/AADA SUPPLEMENT #: 61-212+36 APPLICANT: *Attara Inc.*

DRUG: *All Attached*

DATE OF SUBMISSION: *12/13/95*

The Office of Generic Drugs Policy and Procedure Guide #18-90 as revised on January 22, 1992 lists the following criteria for granting expedited review status to a supplemental new drug application. At least one of the criteria must be met.

1. PUBLIC HEALTH NEED. Events that affect the availability of a drug for which there is no alternative.
2. EXTRAORDINARY HARDSHIP ON THE APPLICANT.
 - a. Catastrophic events such as explosion, fire, storm damage.
 - b. Events that could not have been reasonably foreseen, and for which the applicant could not plan. Examples include:
 - ▲ abrupt discontinuation of supply of active ingredient, packaging material, or container closure; and
 - ▲ relocation of a facility or change in an existing facility because of a catastrophic event (see item 2.a.).
3. AGENCY NEED.
 - a. Matters regarding the government's drug purchase program, upon request from the appropriate FDA office.
 - b. Federal or state legal/regulatory actions, including mandated formulation changes or labeling changes if it is in the Agency's best interest.
 - c. Expiration-date extension or packaging change when the drug product is the subject of a government contract award.

RECOMMENDATIONS:

Branch CSO/Chemist
Anna Weikel

Grant/Deny

Signatures & Dates
Anna Weikel 1-4-96

Supervisory Chemist
Paul Schwantz

Grant/Deny

Signature & Date
Paul Schwantz 1/4/96

Division Director
Allen Robinson

Grant/Deny

Signature & Date
Allen Robinson 1/6/96

COMMENTS:

Altana Inc.

RE: **AADA 61-212**
Bacitracin Zinc Ophthalmic Ointment USP

ANDA 80-692
Hydrocortisone Ointment USP, 1%

ANDA 80-198
Lidocaine Ointment USP, 5%

ANDA 87-355
Nitroglycerin Ointment USP, 2%

ANDA 62-129
Nystatin Cream USP 100,000 u/g

ANDA 62-124
Nystatin Ointment USP 100,000 u/g

ANDA 80-029
Sulfacetamide Sodium Ophthalmic Ointment USP, 10%

**E. Fougera & Co.
division of Altana Inc.**

**Re: AADA 60-764
Neomycin and Polymyxin B Sulfates and
Bacitracin Zinc Ophthalmic Ointment USP**

**AADA 62-166
Neomycin and Polymyxin B Sulfates,
Bacitracin Zinc and Hydrocortisone Acetate
Ophthalmic Ointment USP**

**ANDA 19-137
Betamethasone Dipropionate Cream USP, 0.05%**

**ANDA 19-141
Betamethasone Dipropionate Ointment USP, 0.05%**

**ANDA 18-861
Betamethasone Valerate Cream USP, 0.1%**

**ANDA 18-865
Betamethasone Valerate Ointment USP, 0.1%**

**AADA 62-447
Erythromycin Ophthalmic Ointment USP 5 mg/g**

**AADA 62-531
Gentamicin Sulfate Cream USP, 0.1%**

**AADA 62-533
Gentamicin Sulfate Ointment USP, 0.1%**

**ANDA 80-693
Hydrocortisone Cream USP, 1%**

**ANDA 89-414
Hydrocortisone Cream USP, 2.5%**

**ANDA 81-203
Hydrocortisone Ointment USP, 2.5%**

**ANDA 88-168
Fluocinolone Acetonide Ointment USP, 0.025%**

**E. Fougera & Co.
division of Altana Inc.**

**Re: ANDA 88-169
Fluocinolone Acetonide Cream, USP 0.025%**

**ANDA 88-170
Fluocinolone Acetonide Cream, USP 0.01%**

**ANDA 73-030
Fluocinonide Cream USP, 0.05%**

**ANDA 72-933
Fluocinonide Gel USP, 0.05%**

**ANDA 62-599
Nystatin and Triamcinolone Acetonide Cream USP,
100,000 USP nystatin units/1 mg per gram**

**ANDA 62-602
Nystatin and Triamcinolone Acetonide Ointment USP,
100,000 USP nystatin units/1 mg per gram**

**ANDA 85-692
Triamcinolone Acetonide Cream USP, 0.1% & 0.5%**

**ANDA 85-691
Triamcinolone Acetonide Ointment USP, 0.1% & 0.025%**

**ANDA 86-424
Triple Sulfa Vaginal Cream, USP**

**ANDA 62-938
Neomycin and Polymyxin B Sulfates and Dexamethasone
Ophthalmic Ointment USP,**

**Savage Laboratories
division of Altana Inc.**

**Re: NDA 19-138
Alphatrex[®] (Betamethasone Dipropionate Cream USP, 0.05%)**

**NDA 19-143
Alphatrex[®] (Betamethasone Dipropionate Ointment USP, 0.05%)**

**NDA 18-862
Betatrex[®] (Betamethasone Valerate Cream USP, 0.1%)**

**NDA 18-863
Betatrex[®] (Betamethasone Valerate Ointment USP, 0.1%)**

**ANDA 62-597
Mytrex[®] (Nystatin and Triamcinolone Acetonide Cream USP,
100,000 USP nystatin units/1 mg per gram)**

**ANDA 62-601
Mytrex[®] (Nystatin and Triamcinolone Acetonide Ointment USP,
100,000 USP nystatin units/1 mg per gram)**

**ANDA 87-887
Trysul[®] (Triple Sulfa Vaginal Cream USP)**