

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA061212Orig1s006&007

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

Sponsor: Padagis US

Approval Date: June 12, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s006&007
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Reviews / Information Included in this Review
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Medical Review(s)	
Chemistry Review(s)	X
Bio Pharm/Tox Review	
Bioequivalence Review(s)	
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Other Review(s)	
Administrative & Correspondence Documents	

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APPLICATION NUMBER:
ANDA061212Orig1s006&007

APPROVAL LETTER

AADA 61-212/S-006 and S-007

Altana, Inc.
Attn: Virginia Carman
60 Baylis Road
Melville, NY 11747

JUN 12 1995

Dear Madam:

This is in reference to your supplemental antibiotic drug applications dated February 6, 1995, submitted pursuant to 21 CFR 314.70 regarding your abbreviated antibiotic application for Bacitracin Ophthalmic Ointment, USP.

Reference is also made to your amendments dated May 25, 1995.

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

The material submitted is being retained in our files.

Sincerely yours,

Brenda J. Guerin for 6/9/95
Florence S. Fang
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

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cc: AADA #61-212/S-006 and S-007
DUP/Division File
FIELD COPY
HFD-600/RF

Endorsements:

HFD-643/NSager/06/07/1995/

HFD-643/JHarrison/6/7/95

HFD-617/MAnderson/6/7/95

X:60764s07.rv2

B:

F/T by pah/6/8/95

APPROVAL

*Get for Nancy Sager (ondetail) 6/9/95 -
J Harrison 6/9/95
Mal Anderson 6/9/95*

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APPLICATION NUMBER:
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CHEMISTRY REVIEW(s)

AADA # 60-764/S-007 and S-008 (micro)
✓ 61-212/s-006 and S-007 (micro)
62-938/S-001 and S-002 (micro)

(b) (4)

NAME AND ADDRESS OF APPLICANT:

60-764, 62-166 and 62-938
E. Fougera & Co., division of Altana, Inc.
60 Baylis Road
Melville, NY 11747

61-212
Altana, Inc.
60 Baylis Road
Melville, NY 11747

Attention:
Virginia Carman
(516) 454-7677, ext. 2091

PURPOSE OF AMENDMENT/SUPPLEMENT

(b) (4)

DATE(S) OF SUBMISSION(S)

Submission: 02/06/1995
Receipt: 02/09/1995
Confirmation of receipt: n/a
Request/Labeling review: n/a
Labeling review report: n/a
Request/ADB review: n/a
ADB report: n/a
Request/Bioeq. Waiver: n/a
Bioeq. waiver report: n/a
Request/Est. Evaluation: 05/09/1995
Est. Evaluation report: 05/12/1995
Micro review: 05/11/1995
Amendment: 05/25/1995

PHARMACOLOGICAL CATEGORY

TRADE NAME

NONPROPRIETARY NAME

Antibacterial

See each individual application

DOSAGE FORM

POTENCY

R OR OTC

Ophthalmic Ointment See each application

R

1 Page has been withheld in full as b4
(CCI/TS) immediately following this page

REMARKS AND CONCLUSION

(b) (4) was found acceptable April 28, 1995, see addendum dated 05/11/1995. An acceptable EER was received 05/12/1995.

Approve the supplements for AADA's 60-764, 62-938 and 61-212.

ORDER OF REVIEW

The application submission(s) covered by this review was taken in the date order of receipt.

Yes _____ No X

If no, explain reason(s) below:

Minor amendment which was reviewed ASAP.

DMF CHECKLIST FOR AADA #* REVIEW #2

*60-764/S-007

61-212/s-006

62-938/S-001

<u>DMF#</u>	<u>DMF TYPE</u>	<u>DMF SUBJECT</u>	<u>DMF HOLDER</u>	<u>ACTION CODE</u>	<u>RESULT OF REVIEW</u>	<u>DATE REVIEW COMPLETED</u>
(b) (4)	<u>III</u>	(b) (4)	(b) (4)	<u>1</u>	<u>A</u>	<u>05/08/95</u>
		<u>No relevant CMC information in annual report dated 5/16/1995</u>				
	<u>III</u>	(b) (4)	(b) (4)	<u>3</u>	<u>A</u>	<u>03/20/95</u>
	<u>III</u>	(b) (4)	(b) (4)	<u>3</u>	<u>A</u>	<u>04/12/95</u>
	<u>III</u>	(b) (4)	(b) (4)	<u>1</u>	<u>A</u>	<u>05/08/95</u>
	<u>III</u>	(b) (4)	(b) (4)	<u>3</u>	<u>A</u>	<u>04/12/94</u>
	<u>III</u>	(b) (4)	(b) (4)	<u>3</u>	<u>A</u>	<u>04/16/93</u>

COMMENT :

COMMENT :

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AADA #60-764/S-007 and S-008
61-212/S-006 and S-007
62-938/S-001 and S-002

DUP/Division File
FIELD COPY

Endorsements:

HFD-643/NSager/06/07/1995

HFD-643/JHarrison/6/7/95

X:60764s07.rv2

B:

F/T by pah/6/8/95

per for Nansen Sager 6/9/95 (on detail)
JHarrison 6/9/95