

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA061212Orig1s010

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

Sponsor: Padagis US

Approval Date: July 31, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s010
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APPLICATION NUMBER:
ANDA061212Orig1s010

APPROVAL LETTER

ANDA 61-212/S-010

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

JUL 31 2002

Dear Madam:

This is in reference to your supplemental new drug application, dated February 27, 2002, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Bacitracin Ophthalmic Ointment USP, 500 units/gram. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title 1 of the FDA Modernization Act of 1997.

This supplemental application, submitted as a "Prior Approval Supplement", provides for the following change:

S-010: Revisions in the manufacturing process

We have completed the review of this supplemental application and it is 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,

U.V. Vaidyanathan

7/25/02

for

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

cc: ANDA 61-212/S-010
Field Copy
Division File
HFD-92

Endorsements:

HFD-640/TCLWang/7/15/02 *TCL Wang 7/24/02*
HFD-640/SRosencrance/7/18/02 *MR Rosencrance 7/24/02*
HFD-617/THinchliffe/7/18/02 *THinchliffe 7/24/02*

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F/T by rad7/24/02

TYPE OF LETTER: APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA061212Orig1s010

CHEMISTRY REVIEW(s)

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Supplemental Application Review

ANDA: 61-212/S-010

NAME AND ADDRESS OF APPLICANT:

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

PURPOSE OF AMENDMENT/SUPPLEMENT

S-010: Provides for revisions in the manufacturing process

DATE(S) OF SUBMISSION(S)

Prior approval supplemental application submitted on 2/27/02.

PHARMACOLOGICAL CATEGORY

Ophthalmic Antibiotics

TRADE NAME

N/A

NONPROPRIETARY NAME

Bacitracin Ophthalmic Ointment USP

DOSAGE FORM

Ointment

POTENCY

500 units/gram

RX OR OTC

Rx

SAMPLES

N/A

RELATED IND/NDA/DMF

N/A

STERILIZATION

(b) (4)

LABELING

No Change

BIOEQUIVALENCY STATUS

No Change

ESTABLISHMENT INSPECTION

N/A

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

The firm proposed the following changes in the manufacturing process:

(b) (4)

(b) (4)

(b)(4)

The firm provided the proposed and current blank manufacturing instructions (Attachment II and II). The proposed manufacturing instructions include the revision as mentioned above and other minor changes.

The executed batch record for a (b)(4) exhibit batch, Lot E69, which was manufactured according to the proposed manufacturing instructions, is provided in Attachment III.

Lot E69:

(b)(4)

In-process testing results are found meeting the specifications (pp. 137-138). In-process assay of 12 samples throughout the batch is found satisfactory and thus provides the validation for the mixing procedure. Finished product analysis results are provided on pp. 140-142. Testing results conform to the requirements.

PACKAGING

No Change

STABILITY

The exhibit lot was placed on accelerated and room temperature stability. The 3-month accelerated and 6-month room temperature stability data are found satisfactory.

REMARKS AND CONCLUSION

Approvable

RECALLS

N/A

Reviewer

Tao-Chin L. Wang

ORDER OF REVIEW:

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

No _____

If no, explain reason(s) below.

cc: ANDA 61-212/S-010
Division File
Field Copy

Endorsements:

HFD-640/TCLWang/7/15/02 *TCLWang 7/24/02*
HFD-640/SRosencrance/7/18/02 *MM Rosencrance 7/24/02*
HFD-617/THinchliffe/7/18/02 *u.v. Venhataran for F. Tang*

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F/T by rad7/22/02

TYPE OF LETTER: Approvable