CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 061212Orig1s005

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

Sponsor: Padagis US

Approval Date: February 24, 1995

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ANDA061212Orig1s005

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APPLICATION NUMBER:

ANDA061212Orig1s005

APPROVAL LETTER

61-212

AADA 62-212 (S-005)

19 DEC 1989

E. Fougera & Co.
Division of Altana, Inc.
Attention: Andrew G. Clair, Ph.D.-Reg. Affairs
60 Bayliss Road
Melville, NY 11747

Dear Sir:

Reference is made to your supplemental antibiotic drug application submitted pursuant to Section 314.70 of the Regulations, dated January 23, 1989, regarding your abbreviated antibiotic drug application for Bacitracin Ophthalmic Ointment, 500 units/gram.

We acknowledge receipt of the amendment containing final printed labeling submitted August 16, 1989.

The supplemental application provides for packaging the product in one gram unit-dose containers.

We have completed the review of this supplemental application and it is approved. Our letter of November 9, 1971 detailed the conditions relating to the approval of this abbreviated application.

The material submitted is being retained as part of your application.

Sincerely yours,

Robert A. Jeun for

Acting Director
Division of Generic Drugs
Center for Drug Evaluation and Research

12/15/89

cc:
HFD-235
HFD-235/RF
JHarrison
mw 12/8/89 6511d

12/15/89

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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LABELING

fougera®

BACITRACIN OPHTHALMIC OINTMENT USP STERILE

DESCRIPTION: Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

ACTION: The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphylococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

INDICATIONS: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

CONTRAINDICATIONS: This product should not be used in patients with a history of hypersensitivity to Bacitracin.

PRECAUTIONS: Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly

[over]

fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

ADVERSE REACTIONS: Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

DOSAGE AND ADMINISTRATION: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

DIRECTIONS FOR USE FOR 1 GRAM UNIT OF USE PLASTIC TUBE: Pull (do not twist) cap off. Verify that plastic tip is in place and unbroken. Replace cap, twist and remove cap. The twisting motion breaks the seal and the tip remains in the cap. Dispense product and discard after use. NOTE: If plastic tip is not evident when the cap is pulled off, do not dispense product.

CAUTION: Federal law prohibits dispensing without prescription.

HOW SUPPLIED: 1/8 oz. [3.5 g] sterile tamper proof tubes, NDC 0168-0026-38. Unit dose carton of 48 [1 g] allets, NDC 0168-0026-11.

E. FOUGERA & CO.
a division of Altana Inc.
MELVILLE, NEW YORK 11747

R4/89

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s005

CHEMISTRY REVIEW(s)

MANUFACTURING AND CONTROLS REVIEW

Antibiotic Application 61-212
Amendment to S-005(submitted August 16, 1989)

Manufacturer: (b) (4) [redacted]

Drug: Bacitiacin Ophthalmic Ointment

Supplemental application S-005, dated January 23, 1989, seeks approval to prepare and market the previously approved product in one gram unit-dose Allet containers. Our letter of May 23, 1989 requested the company to submit specimens of the labeling to be used with the new unit-dose container.

The submission dated August 16, 1989, provides the following labeling:

1. Inmediate container-acceptable.
2. Package insert-shows revison dated of 4/89. This revision includes a new section on "Directions for Use for 1 Gram Unit of Use Plastic Tube" and expansion of the "How Supplied"section to include mention of the new unit dose container.-Revised insert is acceptable.
3. Carton for holding 48 unit dose containers-acceptable.

Summary:

This amendment provides final printed specimens of the labeling to be used with new unit-dose containers of Bacitracin Ophthalmic Ointment. The supplemental application dated January 23, 1989, as amended August 16, 1989, is complete and can be approved.

John D. Harrison 12/8/89

6511d

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s005

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

94 JUN 27 8:57

Altana, Inc.
Attention: Ms. Marcy J. Adrian
60 Baylis Road
Melville, New York 11747

JUN 24 1994

Dear Ms. Adrian:

This letter is in response to your April 5, 1994, request for the Office of Generic Drugs' (OGD) comments on your proposal for (b) (4) (b) (4) The Office has reviewed your request and provides the following comments:

(b) (4)

2. Pre-approval supplements will be needed for all products to make the change. The supplements should be submitted as a group as described in the April 8, 1994, letter to industry. In addition, all other appropriate information to support such a change (b) (4) (b) (4) etc.) should be submitted in each supplement. Further, we suggest you submit the supplements in accord with 21 CFR 314.70(b), "Supplement - Expedited Review Requested."

3. Please contact the Office of Over-the-Counter (OTC) Drug Evaluation for guidance on OTC products which are not the subject of an abbreviated new drug application or an abbreviated antibiotic application. These products are not reviewed by OGD.

This letter addresses only the proposed protocol. Other issues may arise upon review of the supplements.

In future correspondence regarding this issue, please include a copy of this letter along with a copy of the your proposal. If you have any questions, please call Ms. Khyati Roberts at (301) 594-0315.

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Sincerely yours,

Robert Pollock for

Douglas L. Sporn
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research