

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**ANDA061212Orig1s004**

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

**Sponsor:** Padagis US

**Approval Date:** March 17, 1989

# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*  
**ANDA061212Orig1s004**  
**CONTENTS**

<b>Reviews / Information Included in this Review</b>
--

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

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA061212Orig1s004**

**APPROVAL LETTER**

AADA 61-212/S-004

Pharmaderm  
Division of Altana, Inc.  
Attention: Andrew G. Clair, Ph.D.  
60 Baylis Road  
Melville, N.Y. 11747

17 MAR 1989

Dear Sir:

Reference is made to your supplemental antibiotic drug application submitted pursuant to Section 314.70 of the Regulations, dated January 18, 1989, regarding your abbreviated antibiotic drug application for Bacitracin Ophthalmic Ointment, USP.

The supplemental application provides for an [REDACTED]

(b) (4)

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,

*Marvin Seife*

Marvin Seife, M.D.  
Director  
Division of Generic Drugs  
Office of Drug Standards  
Center for Drug Evaluation and Research

for

3-17-89

HFD-235  
HFD-235/OD  
JHarrison/J&Singer/bcw/3-15-89  
R/D init M. Seife  
5887d Approval

*John M. Singer 3/16/89*

*for 3/16/89*

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*  
**ANDA061212Orig1s004**

**CHEMISTRY REVIEW(s)**

Manufacturing and Controls Review  
#61-212

Bacitracin Ophthalmic Ointment, USP  
Pharmaderm

Material Reviewed: S-004 dated January 18, 1989

Applicant's submission proposes an alternate sterilization contractor.

1. Contract Sterilizer: (b) (4)
2. Establishment Evaluation Request - satisfactory. See memo from HFD-320 dated January 27, 1989.
3. Validation report for sterilization of ophthalmic ointment tubes at (b) (4) satisfactory.
4. (b) (4) analysis - satisfactory.

Recommendation - the supplement can be approved.

*John M. Singer*  
John M. Singer

Manufacturing and Controls Review

(b) (4)

61-212

Bacitracin  
Pharmaderm

(b) (4)

Ophthalmic Ointment, USP

Material Reviewed : 5-00<sup>4</sup> dated January 18, 1989

Applicant's submission proposes an alternate sterilization contractor.

1. Contract Sterilizer :

(b) (4)

2. Establishment Evaluation Request - satisfactory. See memo from HFD-320 dated January 27, 1989.

3. Validation report for sterilization of ophthalmic ointment tubes at (b) (4) - satisfactory.

4 (b) (4) - satisfactory.

Recommendation - the supplement can be approved.

John M. Singer  
3/15/89