CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 061212Orig1s012

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

Sponsor: Padagis US

Approval Date: May 01, 2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

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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)	
Statistical Review(s)	
Microbiology Review(s)	**X**
Other Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 061212/S-012

Fera Pharmaceuticals LLC
Attention: John D'Angelo
134 Birch Hill Road,
Locust Valley, NY 11560

Dear Sir:

This is in reference to your supplemental new drug application dated December 11, 2009, 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/g.

Reference is also made to the complete response letter issued by this office on February 25, 2013 and your amendment dated March 06, 2013.

The supplemental application, submitted as a "Supplement-changes Being Effected in 30 Days", provides for a site change for the manufacturing, packaging, and testing of the subject product to (b) (4)

We have completed the review of your 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 Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dose forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

PAUL SCHWARTZ
05/01/2013
Signed for K. Uhl

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

LABELING

BACITRACIN OPHTHALMIC OINTMENT USP

STERILE

1000

℞only

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 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.

HOW SUPPLIED: 3.5 g (1/8 Oz) sterile tamper proof tubes, NDC 48102-007-35.

FERA

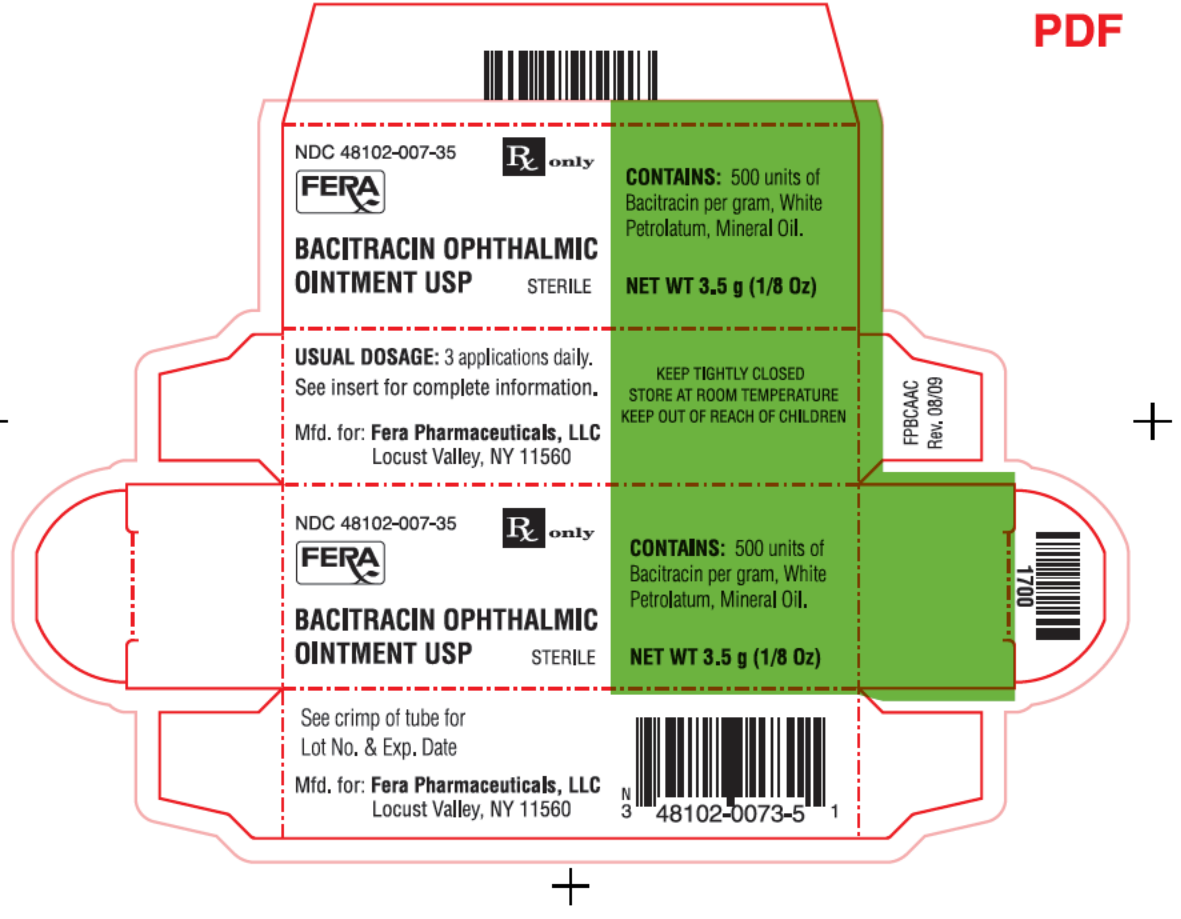
Manufactured for:
Fera Pharmaceuticals, LLC
Locust Valley, NY 11560

FPBC00N Rev. 08/09

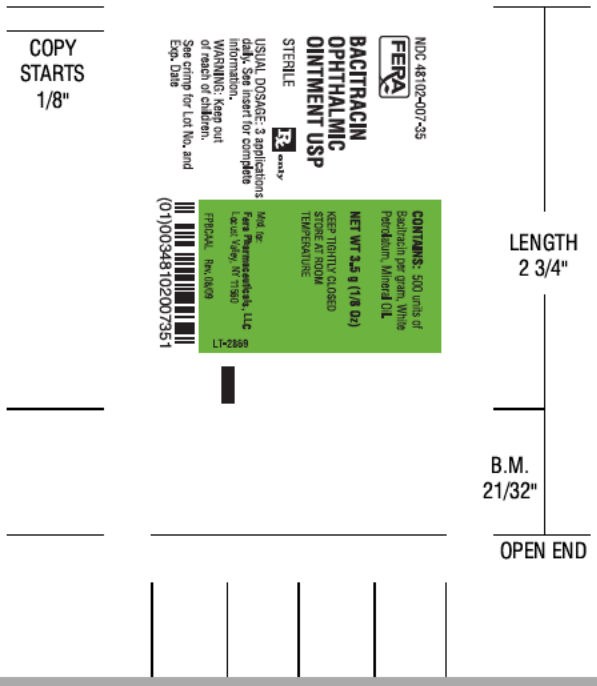
(b) (4)

6551

PDF


NDC 48102-007-35
Rx only
FERA
BACITRACIN OPHTHALMIC OINTMENT USP STERILE
CONTAINS: 500 units of Bacitracin per gram, White Petrolatum, Mineral Oil.
NET WT 3.5 g (1/8 Oz)
USUAL DOSAGE: 3 applications daily. See insert for complete information.
Mfd. for: Fera Pharmaceuticals, LLC Locust Valley, NY 11560
KEEP TIGHTLY CLOSED
STORE AT ROOM TEMPERATURE
KEEP OUT OF REACH OF CHILDREN
FPBCAAC Rev. 08/09
1700
See crimp of tube for Lot No. & Exp. Date
N 3 48102-0073-5 1

(b) (4)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1/8"
NDC 48102-007-35
FERA
BACITRACIN
OPHTHALMIC
OINTMENT USP
STERILE
USUAL DOSAGE: 3 applications daily. See insert for complete information.
WARNING: Keep out of reach of children.
See crimp for Lot No. and Exp. Date
CONTAINS: 500 units of Bacitracin per gram, White Petrolatum, Mineral Oil.
NET WT 3.5 g (1/8 Oz)
KEEP TIGHTLY CLOSED
STORE AT ROOM TEMPERATURE
Mfd. for:
Fera Pharmaceuticals, LLC
Lake Success, NY 11042
FPBOAL Rev. 08/09
LT-2869
(01)00348102007351
LENGTH
2 3/4"
B.M.
21/32"
OPEN END

(b) (4)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

LABELING REVIEW(s)

Labeling Review Branch
Division of Labeling and Program Support
Office of Generic Drugs

Labeling Supplement Review Combined with Chemistry

NO REMS REQUIRED

Application Number: 61-212/S-012 combined with Chemistry

Name of Drug: Bacitracin Ophthalmic Ointment, USP

Applicant: Fera Pharmaceuticals, LLC

Material Reviewed: Package Insert, Container, Carton

Submission Date: December 11, 2009 (Received December 15, 2009)

Background and Summary

1. This CBE supplement provides for a change in manufacturing, packaging and testing site.
2. Firm submitted labels and labeling to revise their manufacturing statement. There was no other changes made to the labels and labeling.
3. **Future Revisions:** YES

- **CONTAINER:** (3.5 gram):
  a. Separate your established name from your text "sterile". (b) (4)
  b. Usual Dosage: Revise "3 applications daily" (b) (4) In addition, (b) (4) "See insert for complete information" (b) (4) (b) (4)
  d. Recommend revising "CONTAINS: 500 units of (b) (4) 500 units of bacitracin in a base of white petrolatum and mineral oil".
  e. Please assure all the information presented on your label is clear and readable, especially the established name and strength.
- **CARTON:** (3.5 gram):
  a. Usual Dosage: Revise "3 applications daily" (b) (4) (b) (4)
  c. Please assure you separate the product strength from the text "sterile". (b) (4)
- **INSERT:** (b) (4)

Review

1. **Container**: Revised manufacturing statement to read as "Manufactured for: Fera Pharmaceuticals, LLC". Satisfactory in FPL as of December 11, 2009 electronic submission.
2. **Carton**: Revised manufacturing statement to read as "Manufactured for: Fera Pharmaceuticals, LLC". Satisfactory in FPL as of December 11, 2009 electronic submission.
3. **Insert:** Revised manufacturing statement to read as "Manufactured for: Fera Pharmaceuticals, LLC". Satisfactory in FPL as of December 11, 2009 electronic submission.

Recommendations

Labeling Supplement is recommended for approval with the above recommended future revisions.

Approve the labeling supplement

{see appended electronic signature}

_____
Beverly Weitzman
Labeling Reviewer

Supervisory Comment/Concurrence:

{see appended electronic signature}

_____
John Grace
Team Leader

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/s/

BEVERLY WEITZMAN
10/22/2012

JOHN F GRACE
10/22/2012

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

CHEMISTRY REVIEW(s)

Final version for DARRTS 4/29/13
APPROVABLE . CMC, Micro and Labeling and EEs are acceptable
HFD-627/R. Chang/04/15/2013
HFD-627/James Fan/4/19/13
Andre Raw/4/29/13
HFD-617/T. Mazza/4/29/13

Office of Generic Drugs
Supplement Review

ANDA: 061212/S-012 REVIEW NO.: 2

NAME AND ADDRESS OF APPLICANT:
Fera Pharmaceuticals
134 Birch Hill Road
Locust Valley, NY 11560

PURPOSE OF AMENDMENT/SUPPLEMENT:
The supplemental application provides for a site change for the manufacturing, packaging and testing of the subject product.

DATE OF SUBMISSION:
Original Submission: December 11, 2009
Amendment: April 22, 2010
Amendment: March 06, 2013

PHARMACOLOGICAL CATEGORY:
Antibacterial

TRADE NAME:
N/A

NONPROPRIETARY NAME:
Bacitracin Ophthalmic Ointment USP, 500 units/gm

DOSAGE FORM:
Ointment

STRENGTHS:
500 units/g

RX OR OTC:
RX

SAMPLES:
N/A

RELATED IND/NDA/DMF:
N/A

STERILIZATION:
Microbiology review is acceptable by Eric Adeeku on 07/16/2010

LABELING:
Acceptable by B. Weitaman on 10/22/2012.

BIOEQUIVALENCY STATUS:
N/A

ESTABLISHMENT INSPECTION:
EER is acceptable on 08/31/2012.

COMPONENTS/COMPOSITION/MANUFACTURING/CONTROLS:
No change

COMPONENTS AND COMPOSITIONS:
No change

OTHER FIRM:
N/A

(b) (4)

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DMF CHECKLIST FOR ANDAs (061212/S-012)

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
N/A				

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").

Reviewer	Signature	Date

cc: ANDA 061212/S012
Division File
Field Copy

Endorsements:
HFD-627/R. Chang/04/15/2013
HFD-627/James Fan/
HFD-617/T. Mazza/

F/T by:

Approvable

Office of Generic Drugs
Supplement Review

ANDA: 061212/S-012

NAME AND ADDRESS OF APPLICANT:
Fera Pharmaceuticals
134 Birch Hill Road
Locust Valley, NY 11560

PURPOSE OF AMENDMENT/SUPPLEMENT:
The supplemental application provides for a site change for the manufacturing, packaging and testing of the subject product.

DATE OF SUBMISSION:
Original Submission: December 11, 2009
Amendment: April 22, 2010

PHARMACOLOGICAL CATEGORY:
Antibacterial

TRADE NAME:
N/A

NONPROPRIETARY NAME:
Bacitracin Ophthalmic Ointment USP, 500 units/gm

DOSAGE FORM:
Ointment

STRENGTHS:
500 units/g

RX OR OTC:
RX

SAMPLES:
N/A

RELATED IND/NDA/DMF:
N/A

STERILIZATION:
Microbiology review is acceptable by Eric Adeeku on 07/16/2010

LABELING:
The supplement contains labeling information, which is pending review (supplement dated 12/11/2009).

BIOEQUIVALENCY STATUS:
N/A

ESTABLISHMENT INSPECTION:
EER is acceptable on 08/31/2012.

COMPONENTS/COMPOSITION/MANUFACTURING/CONTROLS:
No change

COMPONENTS AND COMPOSITIONS:
No change

OTHER FIRM:
N/A

(b) (4)

PACKAGING:
N/A

STABILITY:
Three months accelerated and long term stability data presented (Pack size: 3.5 g and horizontal orientation, Lot #PD09006) are satisfactory.

REMARKS AND CONCLUSION:
Not approval is recommended.

RECALLS:
N/A

REVIEWER:
Richard Chang

Date OF REVIEW:
09/29/2012

DMF CHECKLIST FOR ANDAs (061212/S-012)

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
N/A				

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").

Reviewer	Signature	Date

cc: ANDA 061212/S012
Division File
Field Copy

Endorsements:
HFD-627/R. Chang/09/29/2012
HFD-627/James Fan/
HFD-617/T. Tran/

F/T by:

NOT APPROVAL – Minor Amendment, Labeling information submitted pending review

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

MICROBIOLOGY REVIEW(s)

Product Quality Microbiology Review

June 23, 2010

ANDA: 061212/S-012

Drug Product Name
Proprietary: N/A
Non-proprietary: Bacitracin Ophthalmic Ointment, USP

Review Number: #2

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
04/28/2010	05/04/2010	N/A	05/11/2010
05/26/2010	06/03/2010	N/A	05/27/2010

Submission History (for amendments only)

Date(s) of previous submission(s)	Microbiology Review #	Date(s) of previous Micro Review(s)
12/11/2009	1	03/17/2010

Applicant/Sponsor
Name: Fera Pharmaceuticals LLC
Address: 15R Birch Hill Road, Locust Valley, NY 11560

Representative: Susan McDougal
Telephone: (b) (6)

Name of Reviewer: Eric Adeeku, Ph.D

Conclusion: The submission **is recommended** for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: CBE-30 supplement amendment

2. SUBMISSION PROVIDES FOR: The use of an alternate facility for manufacturing, packaging and testing.

(b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile Ophthalmic Ointment, 500 IU/g multi-dose vials

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: N/A

B. SUPPORTING/RELATED DOCUMENTS:
None

C. REMARKS:
The subject amendment provides responses to the microbiology deficiencies conveyed to the applicant in the Agency's 03/26/2010 deficiency letter.

Further data requested from applicant's representative, Ms. Susan McDougal on 05/13/2010 was provided on 05/27/2010. Please see Tcon Memo attached.

This is an electronic submission.

filename: 061212s12a1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

The submission is **recommended** for approval on the basis of sterility assurance.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable –

N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –

(b) (4)

B. Brief Description of Microbiology Deficiencies -

None identified.

C. Assessment of Risk Due to Microbiology Deficiencies -

No microbiology deficiencies were identified. The applicant demonstrates an adequate level of sterility assurance for the manufacturing process.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Microbiologist/ Eric Adeeku, Ph.D
Microbiology Team Leader/Lynne Ensor, Ph.D.

C. CC Block

cc: Field Copy

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(b) (4)

Acceptable

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-61212	SUPPL-12	ALTANA INC	BACITRACIN

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/s/

ERIC K ADEEKU
07/15/2010

ELIZABETH T MCNEAL on behalf of MARK D ANDERSON
07/15/2010
Checked file and submission links. All correct.

LYNNE A ENSOR
07/16/2010

Product Quality Microbiology Review

March 17, 2010

ANDA: 061212/S-012

Drug Product Name
Proprietary: N/A
Non-proprietary: Bacitracin Ophthalmic Ointment, USP

Review Number: #1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
12/11/2009	12/15/2009	N/A	01/13/2010

Submission History (for amendments only)
None

Applicant/Sponsor
Name: Fera Pharmaceuticals LLC
Address: 15R Birch Hill Road, Locust Valley, NY 11560

Representative: Susan McDougal
Telephone: (b) (6)

Name of Reviewer: Eric Adeeku, Ph.D

Conclusion: The submission **is not recommended** for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: CBE-30 supplement

2. SUBMISSION PROVIDES FOR: The use of an alternate facility for manufacturing, packaging and testing.

(b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile Ophthalmic Ointment, 500 (b) (4)

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: N/A

B. SUPPORTING/RELATED DOCUMENTS:
None

C. REMARKS:
Supplement providing for a site change for the manufacturing, packaging and testing of the subject drug product, since the ANDA was recently purchased by Fera from Nycomed, (b) (4)

filename: 061212s012.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments and deficiencies are provided in the "Product Quality Microbiology Assessment" and "List of Microbiology Deficiencies and Comments" sections.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable –

N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –

(b) (4)

B. Brief Description of Microbiology Deficiencies -

Please see section "3. List of microbiology deficiencies and comments" for details.

C. Assessment of Risk Due to Microbiology Deficiencies -

The safety risk associated with the microbiology deficiencies is considered moderate.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Microbiologist/ Eric Adeeku, Ph.D
Microbiology Team Leader/Lynne Ensor, Ph.D.

C. CC Block

cc: Field Copy

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(b) (4)

[redacted]

Acceptable

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-61212	SUPPL-12	ALTANA INC	BACITRACIN

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/s/

ERIC K ADEEKU
03/24/2010

ELIZABETH T MCNEAL
03/24/2010
Checked file and submission link. Both correct.

LYNNE A ENSOR
03/26/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA061212Orig1s012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

ANDA 061212/S-012

COMPLETE RESPONSE

Fera Pharmaceuticals, LLC
Attention: Dietrich Bartel
Regulatory Consultant
15 R Birch Hill Road
Locust Valley, NY 11560

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) 061212/S-012, dated December 11, 2009, received on December 15, 2009, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application (ANDA) for Bacitracin Ophthalmic Ointment USP, 500 units/gram.

We acknowledge receipt of your amendments dated April 22, April 28, and May 26, 2010.

This supplemental application, submitted as a "Changes Being Effected in 30 Days" provides for a site change for the manufacturing, packaging, and testing of the subject product.

We have completed our review of this sANDA, as amended, and have determined that we cannot approve this supplement in the present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

1. Please provide a copy of the executed exhibit batch record and the location of new manufacturing, packaging, and testing site.
2. Please provide your updated drug product release specification along with a CoA for your Exhibit batch.

MICROBIOLOGY

The Division of Microbiology has no further questions at this time.

LABELING

The Labeling Review Branch has no further questions/comments at this time based on your labeling submission dated (December 11, 2009).

OTHER

A partial response to this letter will not be processed as a resubmission and will not start a new review cycle. The resubmission to this will be considered to represent a **MINOR** AMENDMENT. The designation as a **RESUBMISSION/AFTER ACTION MINOR / COMPLETE RESPONSE AMENDMENT** should appear prominently in your cover letter. In addition, please designate in bold on your cover letter each review discipline (Product Quality (CMC), Labeling, Bioequivalence, Microbiology, Clinical) you are providing responses to.

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the sANDA under 21 CFR 314.65. You may also request an extension of time in which to resubmit the sANDA. A resubmission response must fully address all the deficiencies listed.

If you have any questions, please call Esther Chuh, Pharm.D., Regulatory Project Manager, at (240) 276-8530.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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/s/

PAUL SCHWARTZ
02/25/2013
Signed for G. Geba

ANDA 061212/S-012

Fera Pharmaceuticals
Attention: Dietrich Bartel
134 Birch Hill Road,
Locust Valley, NY 11560

Dear Sir:

This is in reference to your supplemental new drug application dated December 11, 2009, 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/g.

Reference is also made to your amendment dated April 22, 2010.

The supplemental application, submitted as a "Supplement-changes Being Effected in 30 Days", provides for a site change for the manufacturing, packaging, and testing of the subject product.

The supplemental application is deficient and, therefore, not approvable under Section 505 of the Act for the following reasons:

1. Please provide a copy of the executed exhibit batch record and the location of new manufacturing, packaging, and testing site.
2. Please provide your updated drug product release specification along with a CoA for your Exhibit batch.

The file on this supplemental application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw this supplemental application. Your amendment should respond to all the deficiencies listed. A partial reply will not be considered for review, nor will the review clock be reactivated until all the deficiencies have been addressed. The response to this letter will be considered as a MINOR amendment and should be so designated in your cover letter.

If you have substantial disagreement with our reason for not approving this supplemental application, you may request an opportunity for a hearing.

Sincerely yours,

{See appended electronic signature page}

Andre Raw, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 061212/S-012
Division File
Field Copy

Endorsements:
HFD-627/R. Chang/09/20/2012
HFD-627/James Fan/
HFD-617/Trang Tran/10/15/12

F/T by:

TYPE OF LETTER: NOT APPROVAL – Minor Amendment. Labeling information submitted is pending review. Micro & EES are AC.

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/s/

RICHARD R CHANG
10/15/2012

TRANG Q TRAN
10/15/2012

JAMES M FAN
10/15/2012