CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 65-024

ADMINISTRATIVE DOCUMENTS

RECORD OF TELEPHONE CONVERSATION

DATE: August 24, 1998

DRUG PRODUCT: Gentamicin Sulfate

ANDA NUMBER: 65-024

COMPANY: Altana

NAME OF COMPANY REPRESENTATIVE(S): Virginia Carman

NAME OF OGD REPRESENTATIVE(S): Nasser Mahmud

Telecon initiated by: Nasser Mahmud

COMPANY TELEPHONE: 516-454-7677

I called Virginia to request 3 additional copies of all labeling and a side by side comparison of all labeling.

TELEPHONE MEMO

ANDA/DMF#: **ANDA 65-024**
FIRM: **Altana**
PARTICIPANTS: **Marla Stevens-Riley-FDA** M. Stevens-Riley 5/30/03
Audrey Zaweski-Altana
DATE: **5/30/03**
SUBJECT: **Gentamicin Sulfate Ophthalmic Ointment USP 0.3%**
REQUESTED BY: **FDA**

Dr. Stevens-Riley asked the following questions:

1. [redacted]

2. Attachment XIX of the May 7, 2003 amendment does not contain the information specified in question 2b. It contains a list of SOPs. Please clarify.

3. Regarding the June 18, 2002 amendment micro issues: Dr. Stevens-Riley did not look at the batch records in details, so any changes were not realized. The Microbiology reviewers do not look at batch records in detail. It is better to provide a narrative/text description in the sterility assurance section (of the manufacturing process and other details) rather than just submitting batch records. Batch records can be difficult to follow. Also, does Attachment IV of the May 7, 2003 amendment contain a synopsis of all of the manufacturing changes that were made between the original submission exhibit batch and the June 18, 2002 amendment exhibit batch? Is there more information that needs to be submitted?

It was agreed that Ms. Zaweski would research the answers to the above questions and call Dr. Stevens-Riley on Tuesday or Wednesday of next week to determine if a telephone amendment would need to be submitted.

Filename: V/FirmsAM/Altana/Telecons/65024MicroMay3003.doc
CC: ANDA 65-024
CC: Division File

TELEPHONE MEMO

ANDA/DMF#: **ANDA 65-024**
FIRM: **Altana**
PARTICIPANTS: **Marla Stevens-Riley-FDA** M-Stevens-Riley 6/11/03
Audrey Zaweski-Altana
DATE: **6/11/03**
SUBJECT: **Gentamicin Sulfate Ophthalmic Ointment USP 0.3%**
REQUESTED BY: **FDA**

Ms. Zaweski provided responses to questions asked in the 5/30/03 teleconference:

1.

Response:

2. Attachment XIX of the May 7, 2003 amendment does not contain the information specified in question 2b. It contains a list of SOPs. Please clarify.

Response: **Question 2b of the May 7, 2003 amendment should refer to Attachment XVI on page 975.**

3. Regarding the June 18, 2002 amendment micro issues: Dr. Stevens-Riley did not look at the batch records in details, so any changes were not realized. The Microbiology reviewers do not look at batch records in detail. It is better to provide a narrative/text description in the sterility assurance section (of the manufacturing process and other details) rather than just submitting batch records. Batch records can be difficult to follow. Also, does Attachment IV of the May 7, 2003 amendment contain a synopsis of all of the manufacturing changes that were made between the original submission exhibit batch and the June 18, 2002 amendment exhibit batch? Is there more information that needs to be submitted?

Response: **Yes, all of the changes in the June 18, 2002 amendment are summarized in Attachment IV of the May 7, 2003 amendment.**

It was agreed that Ms. Zaweski would send in a telephone amendment by fax then followed by a hard copy with the above information.

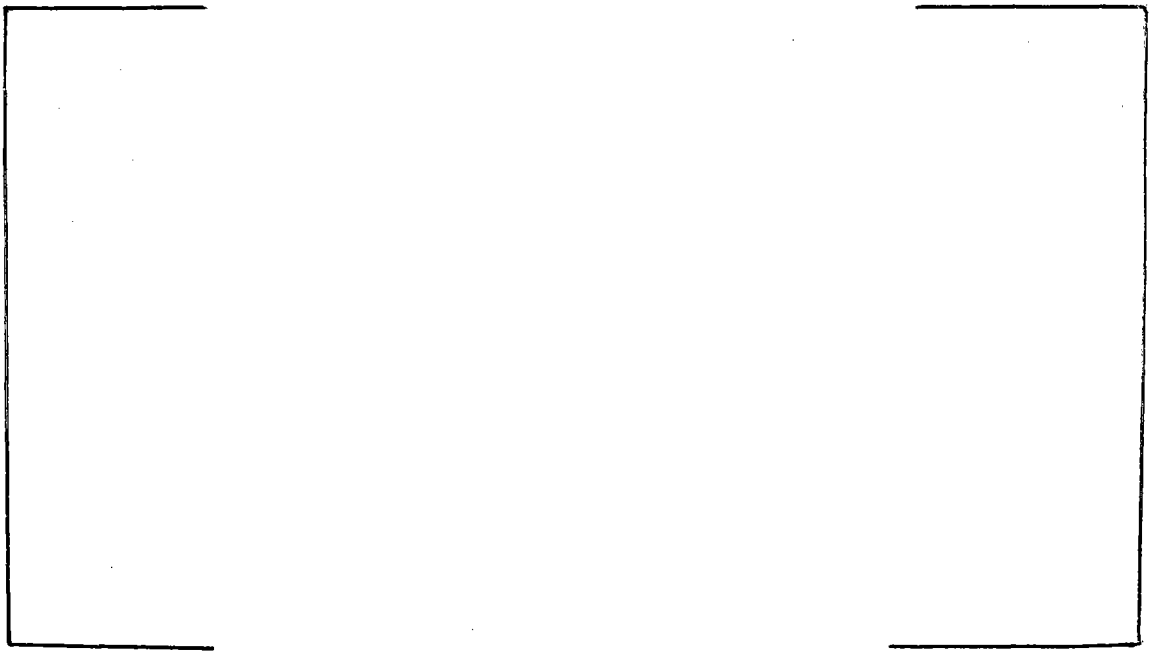
Filename: V/FirmsAM/Altana/Telecons/65024MicroJune1103.doc
CC: ANDA 65-024
CC: Division File

TELEPHONE MEMO

ANDA/DMF#: ANDA 65-024
FIRM: Altana
PARTICIPANTS: Marla Stevens-Riley-FDA
Audrey Zaweski-Altana M. Stevens-Riley 6/20/03
DATE: 6/20/03
SUBJECT: Gentamicin Sulfate Ophthalmic Ointment USP 0.3%
REQUESTED BY: FDA

The following clarification was requested by Dr. Stevens-Riley:

1. With regard to question 10 in the May 7, 2003 amendment: please clarify the role of



It was agreed that Ms. Zaweski would send in a telephone amendment by fax followed by a hard copy with the above information and clarifications. She will call on Tuesday June 24, 2003 to let Dr. Stevens-Riley know of the status of the information and ask any needed questions.

Filename: V/FirmsAM/Altana/Telecons/65024MicroJune2003.doc
CC: ANDA 65-024
CC: Division File

TELEPHONE MEMO

ANDA/DMF#:	**ANDA 65-024**
FIRM:	**Altana**
PARTICIPANTS:	**FDA: Marla Stevens-Riley and Bonnie McNeal** M. Stevens-Riley 6/27/03 B. McNeal 6/27/03 **Altana: Audrey Zaweski-Associate Director of Reg. Affairs, Cindy Anderson-Sr. Reg. Associate, Joan Bahn-Sr. Validation Engineer**
DATE:	**6/26/03**
SUBJECT:	**Gentamicin Sulfate Ophthalmic Ointment USP 0.3%**
REQUESTED BY:	**FDA**

1. Ms. Zaweski provided answers to the questions discussed during the June 20, 2003 teleconference regarding the [redacted]

Redacted 1 page(s)

of trade secret and/or

confidential commercial

information from

6/26/2003 TCON

TELEPHONE MEMO

ANDA/DMF#: **ANDA 65-024**
FIRM: **Altana**
PARTICIPANTS: **FDA: Marla Stevens-Riley** M. Stevens-Riley 6/27/03
Altana: Audrey Zaweski-Associate Director of Reg. Affairs,
DATE: **6/27/03**
SUBJECT: **Gentamicin Sulfate Ophthalmic Ointment USP 0.3%**
REQUESTED BY: **FDA**

1. Dr. Stevens-Riley provided recommendations after discussion with the Microbiology Team Leader for the following issues:

3. Dr. Stevens-Riley also asked if there was
Ms. Zaweski stated that she would have to check on this.

4. Ms. Zaweski inquired about the status of the microbiology review.

Dr. Stevens-Riley stated that she hoped to finish by next week. She informed Ms. Zaweski that there would probably be deficiencies issued. The recent telecons have been for clarification to allow review of the existing amendment. Significant deficiencies are sent out in a letter.

It was decided that Ms. Zaweski would submit a telephone amendment (fax followed by hard copy) with any new specifications based on the above information.

Filename: V/FirmsAM/Altana/Telecons/65024MicroJune2703.doc
CC: ANDA 65-024
CC: Division File

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 65-024

CORRESPONDENCE

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 516-454-7677 Fax: 516-454-6389 BYK GULDEN PHARMA GROUP

August 4, 1998

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

VIA FEDERAL EXPRESS

RE: Original Submission
Abbreviated New Drug Application
Gentamicin Sulfate Ophthalmic Ointment USP

Dear Sir or Madam:

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act and in accordance with 21 CFR §314.94, Altana Inc., is submitting this Abbreviated New Drug Application to market a new drug, Gentamicin Sulfate Ophthalmic Ointment USP.

The reference listed drug that is the basis for this submission is Garamycin® (gentamicin sulfate Ophthalmic Ointment), (NDA 50-425), manufactured by Schering Corporation. The proposed drug, Gentamicin Sulfate Ophthalmic Ointment USP, contains the same active ingredient in the same strength and dosage form, has the same indications and usage, and route of administration as the reference listed drug.

The exhibit batch (# A43) included in this application was fully packaged utilizing the 3.5 gram presentation for which approval is currently requested. The number of units filled and the disposition of any remaining bulk product are reconciled in the exhibit batch record.

Included in this three (3) volume submission, along with Form FDA 356h, is the required Patent Certification and Exclusivity statements, Draft Labeling, Bioequivalence Waiver Request, Full Components and Composition Statements, Raw Materials Controls, description of the Manufacturing Facilities, Manufacturing and Processing Instructions, In-Process Controls, Filling and Packaging Procedures, information on the Container/Closure System, controls for the Finished Dosage Form, Analytical Methods, Finished Dosage Form Stability, Environmental Impact Analysis Statement, Certification Requirements of the Generic Drug Enforcement Act of 1992 and Field Copy Certification.

An additional volume is also included which contains the Sterile Validation Section of the application (Section 11).

All regulatory correspondences related to this Abbreviated New Drug Application should be addressed to:

Virginia Carman
Associate Director
Regulatory Affairs
Altana Inc.
60 Baylis Road
Melville, NY 11747

A certified copy of this application (consisting of three volumes and copies of the Methods Validation Package and In-Process Controls Section) is being sent to the New York District Office under separate cover.

If you require any additional information, please contact me at (516) 454-7677 extension 2091.

Sincerely,
ALTANA, INC.

Virginia Carman

Virginia Carman
Associate Director, Regulatory Affairs

Enclosures

VC/jb

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 516-454-7677 Fax: 516-454-6389 BYK GULDEN PHARMA GROUP

August 27, 1998

FEDERAL EXPRESS

Mr. Nasser Mahmud
Office of Generic Drugs
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD. 20855

ORIG AMENDMENT
[redacted]
AF

RE: **ANDA 65-024 New Correspondence Gentamicin Ophthalmic Ointment**

Dear Mr. Mahmud:

Reference is made to our telephone conversation of August 24, 1998 concerning the above noted application.

As per your request, please find enclosed, in duplicate, three additional copies of our proposed labeling, as well as an annotated side by side comparison of our proposed labeling and the reference listed drug.

We trust that with this additional information the Office will find our application acceptable for filing.

If any further information is required, please contact me at (516) 454-7677 ext. 2091.

Sincerely,
Altana Inc.

Virginia Carman

Virginia Carman
Associate Director
Regulatory Affairs

RECEIVED
AUG 1998
[redacted]

Enclosure

VC:pj

ANDA 65-024

Altana, Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, New York 11747

SEP 17 1998

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to the telephone conversation dated August 24, 1998 and your correspondence dated August 27, 1998.

NAME OF DRUG: Gentamicin Sulfate Ophthalmic Ointment USP, 0.3% (base)

DATE OF APPLICATION: August 4, 1998

DATE (RECEIVED) ACCEPTABLE FOR FILING: August 5, 1998

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Mark Anderson
Project Manager
(301) 827-5849

Sincerely yours,

9/16/98

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 65-024
cc: DUP/Jacket
Division File
Field Copy
HFD-610/J.Phillips
HFD-92
HFD-615/M.Bennett

Endorsement: HFD-615/PRickman, Chief, RSB _____ date 9/16/98
HFD-615/NMahmud, CSO _____ date 9/2/98
HFD-643/JHarrison, Sup. Chem. _____ date
WP File x:\new\firmsam\altana\ltrs&rev\65024.ack
F/T mjl/9/1/98
ANDA Acknowledgment Letter!

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of trade secret and/or

confidential commercial

information from

FDA FAX 3/30/1999 CHEMISTRY COMMENTS

pages 1-2

12.

Sincerely yours,

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

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 65-024

Date of Submission: August 4, 1998 and August 27, 1998

Applicant's Name: Altana, Inc.

Established Name: Gentamicin Sulfate Ophthalmic Ointment, USP

Labeling Deficiencies:

1. CONTAINER: 3.5 g

   a. Front panel

      Add the net quantity 3.5 g.

   b. Back panel

      To be in accord with the USP storage recommendations add the following statement after the storage temperature range:

      Avoid exposure to excessive heat.

   c. We encourage you to revise the color or your cap to "tan". We refer you to the Guidance for Industry for container closure system used for the packaging of Human Drugs, which reserves "tan" for anti-infective products.

2. CARTON: 1 x 1

   See comments under CONTAINER.

3. INSERT

   a. General Comment

      We encourage the inclusion of "USP" following the established name in the Title and in the DESCRIPTION section.

   b. DESCRIPTION

      Revise the second paragraph to read, "...

ointment for topical ophthalmic use. Each gram contains ...".

c. DOSAGE AND ADMINISTRATION

Revise "affected eye" to read "affected eye(s)".

d. HOW SUPPLIED

Include the strength, as seen in your DESCRIPTION section. We refer you to 21 CFR 201.57(k)(1) for further guidance.

Please revise your labels and labeling, as instructed above, and submit in final print.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 65-024

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

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

APR 17 2000

Dear Madam:

This letter is in reference to your Abbreviated New Drug Application (ANDA) dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%.

We refer you to our "Not Approvable" letter dated March 30, 1999, which detailed the deficiencies identified during our review of your ANDA. The Agency may consider an ANDA applicant's failure to respond to a "Not Approvable" letter within 180 days to be a request by the applicant to withdraw the ANDA under 314.120(b). Your amendment to the application is overdue. You must amend your application within 10 days of receipt of this letter. Otherwise, an action to withdraw the application will be initiated per 21 CFR 314.99.

If you do not wish to pursue approval of this application at this time, you should request withdrawal in accord with 21 CFR 314.65. A decision to withdraw the application would be without prejudice to refiling.

Please send all correspondence to the following address:

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Sincerely yours,

for

Wm Peter Rickmam
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA # 65-024
DUP/Division File
HFD-610/PRickman
Endorsement:
HFD-617/NMahmud, Chief, RSB, _____ date 4/17/00
HFD-617/SMiddleton, CSO, _____ date 4/12/00
Word File
V:\FIRMSAM\ALTANA\LTRS&REV\65024.OTH
F/T by mjl/4/11/00
10 DAY LETTER!

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

ALTANA

Will amend by 8/2/00, check Status then 5.11.dd/ltr 5/5/00

May 2, 2000

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NEW CORRESP
NC

Re: ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%

Dear Mr. Rickman:

Reference is made to your communication of April 17, 2000 advising Altana Inc. that our Abbreviated New Drug Application will be withdrawn due to Altana's lack of response to a deficiency letter of March 30, 1999.

Please be advised that a response is in preparation, and will be submitted within 90 days. We, therefore, respectfully request that ANDA 65-024 not be withdrawn at this time.

Thank you for your consideration of our request.

If there are any questions, please contact me at (631) 454-7677 extension 2091.

Sincerely,
Altana Inc.

Virginia Carman

Virginia Carman
Associate Director, Regulatory Affairs

VC/et

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
MAY 03 2000
OGD

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

September 29, 2000 *VIA FEDERAL EXPRESS*

ORIG AMENDMENT
N/AC

Florence Fang, Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
MAJOR AMENDMENT

Dear Ms. Fang:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3% submitted August 4, 1998, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Altana Inc. acknowledges receipt of the following FDA correspondence dated March 30, 1999. As requested, this response has been appropriately identified as a MAJOR AMENDMENT.
For the reviewer's convenience, where applicable, attachments containing replacement pages have been paginated in accordance with the page numbers submitted in the original application.

Each item has been addressed in **comment**/response format.

Chemistry Deficiencies

1.

Redacted 8 page(s)

of trade secret and/or

confidential commercial

information from

ALTANA 9/29/2000 LETTER

Labeling Deficiencies:

1. **CONTAINER: 3.5g**

   a **Front panel**

   Add the net quantity 3.5g.

   b. **Back panel**

   To be in accord with the USP storage recommendations add the following statement after the storage temperature range:

   Avoid exposure to excessive heat.

   The container label has been revised to include the net quantity "3.5 g." The statement "Avoid exposure to excessive heat." has been provided after the storage temperature range. Please refer to Attachment XI for copies of final printed labeling.

   c. **We encourage you to revise the color or your cap to "tan". We refer you to the Guidance for Industry for container closure system used for the packaging of Human Drugs, which reserves "tan" for anti-infective products.**

   Altana acknowledges your recommendation to utilize tan caps as requested by the *American Academy of Ophthalmology*. While it is true that caps of most ophthalmic solution bottles are white or color coded, the standard cap color for ophthalmic ointment tube/cap configurations is black.

2. **CARTON: 1 x 1**

   See comments under CONTAINER.
   The carton labeling has been revised to include the net quantity "3.5 g." The container label has been revised to include the net quantity "3.5 g." The statement "Avoid exposure to excessive heat." has been provided after the storage temperature range. Please refer to Attachment XI for copies of final printed labeling.

3. **INSERT:**

   a. **General Comment**

   We encourage the inclusion of "USP" following the established name in the Title and in the DESCRIPTION section.

   The designation, "USP" has been provided after "Gentamicin Sulfate Ophthalmic Ointment" in both the Title and in the DESCRIPTION section of the package insert labeling.

b. DESCRIPTION

Revise the second paragraph to read, "..ointment for topical ophthalmic use. Each gram contains...".

The second paragraph of the DESCRIPTION section of the package insert labeling has been revised to read "Gentamicin Sulfate Ophthalmic Ointment USP is a sterile ointment for topical ophthalmic use. Each gram contains..." Please refer to Attachment XI.

c. DOSAGE AND ADMINISTRATION

Revise "affected eye" to read "affected eye (s)".

The statement under the DOSAGE AND ADMINISTRATION section of the package insert labeling has been revised to read "Apply a small amount (about ½ inch) to the affected eye(s) two to three time a day." Please refer to Attachment XI.

d. HOW SUPPLIED

Include the strength, as seen in your DESCRIPTION section. We refer you to 21 CFR 201.57(k)(1) for further guidance.

The strength "equivalent to 3 mg gentamicin" has been provided in the HOW SUPPLIED section of the package insert labeling. Please refer to Attachment XI.

Attachment XI contains twelve (12) copies each of Final Printed labeling for the container, carton and package insert.

To facilitate review of this submission, and in accordance with 21 CFR 314.94(a)(8)(iv), we have provided a side-by-side comparison of our current and previously submitted proposed labeling as Attachment XII with all differences annotated and explained.

This concludes our amendment. If you require further information or clarification, please contact me at (631) 454-7677, extension 2091.

Sincerely

ALTANA INC.
Virginia Carman
Virginia Carman
Associate Director
Regulatory Affairs

VC:ca
Enclosures

38. Chemistry Comments to be Provided to the Applicant

ANDA 65-024 APPLICANT: Altana, Inc.

DRUG PRODUCT: Gentamicin Sulfate Ophthalmic Ointment, USP 0.3%

The deficiencies presented below represent MAJOR deficiencies.

Chemistry Deficiencies:

[redacted] For these reasons, you should identify a new supplier for the API, produce a new batch of the finished product, and submit all the appropriate information and performance data.

Sincerely yours,

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

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 65-024

Date of Submission: September 29, 2000

Applicant's Name: Altana, Inc.

Established Name: Gentamicin Sulfate Ophthalmic Ointment, USP

Labeling Deficiencies:

INSERT

a. TITLE

You may delete the statement "Each gram contains ... gentamicin" following the TITLE.

b. PRECAUTIONS

Add the following as the last subsection of this section.

Pediatric Use

Safety and effectiveness in neonates have not been established.

Please revise your insert labeling, as instructed above, and submit final printed labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

William Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 65-024

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

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

MAR 28 2002

Dear Madam:

This letter is in reference to your Abbreviated New Drug Application (ANDA) dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%.

We refer you to our "Not Approvable" letter dated January 30, 2001, which detailed the deficiencies identified during our review of your ANDA. The Agency may consider an ANDA applicant's failure to respond to a "Not Approvable" letter within 180 days to be a request by the applicant to withdraw the ANDA under 314.120(b). Your amendment to the application is overdue. You must amend your application within 10 days of receipt of this letter. Otherwise, an action to withdraw the application will be initiated per 21 CFR 314.99.

If you do not wish to pursue approval of this application at this time, you should request withdrawal in accord with 21 CFR 314.65. A decision to withdraw the application would be without prejudice to refiling.

APPEARS THIS WAY
ON ORIGINAL

If you have further questions you may contact Saundra T. Middleton, Project Manager, Regulatory Support Branch, at (301) 827-5862.

Please send all correspondence to the following address:

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Sincerely yours,

Saundra T. Middleton for

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA # 65-024
DUP/Division File
HFD-610/PRickman
Endorsement:
HFD-617/GDavis, Chief, RSB, S. T. Middleton for date 3/28/02
HFD-617/SMiddleton, CSO, S. T. Middleton date 3/28/02
Word File
V:\FIRMSAM\ALTANA\LTRS&REV\65024-2.OTH
F/T by EEH 03/28/02
10 DAY LETTER!

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

4/22/02 I spoke w/ V. Carman. She hopes to amend the ANDA by the end of June 02 but will call around mid-June for status update. S. Middleton

April 17, 2002

VIA FEDERAL EXPRESS

Document Control Room
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

NEW CORRESP

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
REQUEST TO MAINTAIN OPEN APPLICATION STATUS

Reference is made to the Altana Inc. Abbreviated New Drug Application for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3% submitted August 4, 1998, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to Altana's Amendments dated September 29, 2001 and January 30, 2001 as well as to FDA correspondence dated January 30, 2001 requesting Altana to perform the following in order to obtain approval as [redacted] is not an approvable source of drug substance:

- Identify a new supplier of active pharmaceutical ingredient.
- Manufacture a new batch using this source.

Altana Inc. also acknowledges receipt of the FDA correspondence dated March 28, 2002, which states that Altana must correspond within 10 days of receipt of this said correspondence (received April 9, 2002) in order to continue the approval process of this application.

Altana is requesting the application remain open as Altana has secured a new source of API ([redacted]) and does intend to amend the application with an exhibit batch as soon as satisfactory three month stability is completed.

If you require further information or clarification, please contact me at (631) 454-7677, extension 2091.

Sincerely

ALTANA INC.

Virginia Carman

Virginia Carman
Associate Director, Regulatory Affairs

VC:ca

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

June 18, 2002

VIA FEDERAL EXPRESS

ORIG AMENDMENT
N/AC
EER for requested * mA 9/19/02
(* and update for other sites)

Florence Fang, Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
MAJOR AMENDMENT

Dear Ms. Fang:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3% submitted August 4, 1998, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to Altana's MAJOR AMENDMENT dated September 29, 2001 pursuant to 21 CFR§ 314.96.

Altana Inc. acknowledges receipt of the following FDA correspondence dated January 30 2001. As requested, this response has been appropriately identified as a MAJOR AMENDMENT.

Each item has been addressed in **Comment**/Response format.

Chemistry Deficiencies:

[redacted]

JUN 19 2002

OGD / CDER

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
MAJOR AMENDMENT
June 18, 2002

Labeling deficiencies:

INSERT

a. TITLE

You may delete the statement "Each gram contains…Gentamicin" following the TITLE.

The statement following the title, "Each gram contains… Gentamicin" has been deleted

b. PRECAUTIONS

Add the following as the subsection of this section.

Pediatric Use

Safety and effectiveness in neonates have not been established.

The preceding subsections have been added under PRECAUTIONS.

Attachment IX contains twelve (12) copies each of Final Printed labeling for the container, carton and package insert.

To facilitate review of this submission, and in accordance with 21 CFR 314.94(a)(8)(iv), we have provided a side-by-side comparison of our current and previously submitted proposed labeling as Attachment IX with all differences annotated and explained.

If you require further information or clarification, please contact me at (631) 454-7677, extension 2091.

Sincerely

ALTANA INC.

Audrey Bialeski for/

Virginia Carman
Associate Director, Regulatory Affairs

VC:ca
Enclosures

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number:	65-024
Date of Submission:	June 18, 2002
Applicant's Name:	Altana, Inc.
Established Name:	Gentamicin Sulfate Ophthalmic Ointment, USP

Labeling Deficiencies:

1. CONTAINER: 3.5 g

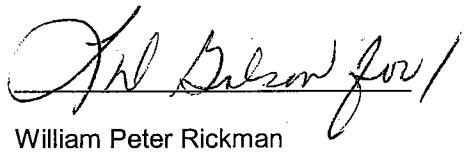
   The side panel of your printer's proof container label is difficult to read. Improve the readability by increasing the print size and/or using darker print.

   Please note, if your final printed container labels provide improved clarity for the text printed on the side panel, you may submit twelve final printed labels for our review

Please revise your container labels, as instructed above, and submit in final print.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.



William Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

41

ALTANA

Altana Inc. 60 Baylis Road, Melville, N.Y. 11747 631-454-7677

August 7, 2002

VIA FEDERAL EXPRESS

Mr. Peter Rickman
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT
N/AF

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
LABELING AMENDMENT

Dear Mr. Rickman:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Gentamicin Sulfate Ophthalmic Ointment USP, 0.3% submitted August 4, 1998, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to Altana's Amendments dated September 29, 2001 and June 14, 2002, respectively.

Altana Inc. acknowledges receipt of the following FDA correspondence dated July 31, 2002.

Each item has been addressed in **comment** / response format.

1. **CONTAINER 3.5 g:**

   The side panel of your printer's proof container label is difficult to read. Improve the readability by increasing the print size and/or using darker print.

   Please note, if your final printed container labels provide improved clarity for the text printed on the side panel, you may submit twelve final printed labels for our review.

   Please revise your container labels, as instructed above, and submit in final print.

Attachment I contains twelve (12) copies of the Final Printed container label.

To facilitate review of this submission, and in accordance with 21 CFR 314.94(a)(8)(iv), we have provided a side-by-side comparison of our current and previously submitted proposed labeling as **Attachment II** with all differences annotated and explained.

If you require further information or clarification, please contact Audrey Bialeski, Manager, Regulatory Affairs at (631) 454-7677, extension 3007. Fax communications may be made to (631) 756-5114.

Sincerely
ALTANA INC.

Virginia Carman

Virginia Carman
Associate Director, Regulatory Affairs

VC:ap

Attachments

RECEIVED
AUG 0 8 2002
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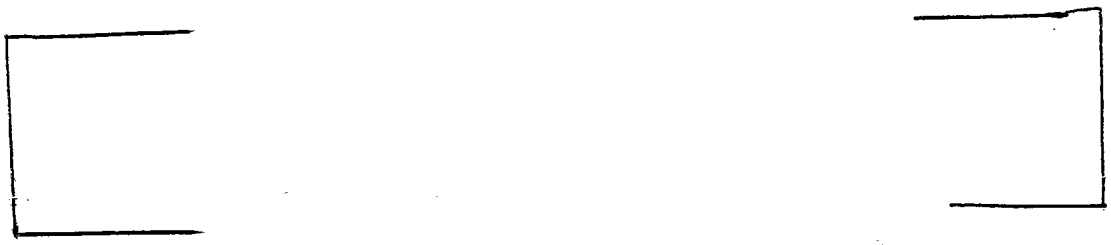
10/24/2002 FDA FAX [CHEMISTRY COMMENTS]

pages 1-2

10. 

B. Please note and acknowledge the following in your response:

The sterility assurance data regarding this finished product is currently under review. Any comments will be forwarded in a separate communication.

Sincerely yours,

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

Pharma

ALTANA

Noted: To Maria
M Anderson

December 9, 2002

ALTANA Inc
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Florence S. Fang
Director
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Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/AM

VIA FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5g
MINOR AMENDMENT

Dear Ms. Fang:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Altana Inc. acknowledges the following FDA correspondence dated October 24, 2002 stating Altana's submission was deficient. Comments as noted in the aforementioned correspondence have been addressed as follows:

This response has been identified as a MINOR AMENDMENT to ANDA 65-024.

Each item has been addressed in **comment** / response format.

Chemistry Comments:

A. Chemistry Deficiencies:

1. [redacted]

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OGD / CDER

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ALTANA 12/9/2002 LETTER

If you require further information or clarification, please contact Audrey Zaweski, *Manager*, Regulatory Affairs, at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Virginia Carman

Virginia Carman.
Associate Director, Regulatory Affairs

VC:ca

Attachments

FEB 20 2003

38. Chemistry Comments to be Provided to the Applicant

ANDA 65-024 APPLICANT: Altana, Inc.

DRUG PRODUCT: Gentamicin Sulfate Ophthalmic Ointment, USP 0.3%

The deficiencies presented below represent MINOR deficiencies.

A. Chemistry Deficiencies:

1.

2.

3.

4.

Sincerely yours,

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

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FDA FAX 2/20/2003 [MICROBIOLOGY COMMENTS]

11.

12.

13.

14.

Please clearly identify your amendment to this facsimile as "RESPONSE TO MICROBIOLOGY DEFICIENCIES". The "RESPONSE TO MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,

Neal J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research

Pharma

ALTANA

May 7, 2003

ALTANA Inc
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Florence S. Fang
Director
Division of Chemistry II
Neil J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

DRUG AMENDMENT
N/AM

VIA FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP,
MINOR AMENDMENT
RESPONSE TO CHEMISTRY DEFICIENCIES
RESPONSE TO MICROBIOLOGY DEFICIENCIES

Dear Ms. Fang and Dr. Sweeney:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to Amendments submitted September 29, 2000 and June 18, 2002.

Altana Inc. acknowledges the following FDA correspondence dated February 20, 2003 stating Altana's submission was deficient.

This response has been identified as a MINOR AMENDMENT to ANDA 65-024.

Each item has been addressed in **comment** / response format.

Chemistry Comments:

Chemistry Deficiencies:

1.

2.

MAY 8 – 2003
OGD / CDITR

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ALTANA LETTER 5/7/2003

12.

13.

14.

If you require further information or clarification, please contact Ms. Audrey Zaweski, Associate Director, Regulatory Affairs at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:ca

Attachments

Pharma

ALTANA

June 12, 2003

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Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
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Rockville, MD 20855-2773

VIA FEDERAL EXPRESS

ORIG AMENDMENT
FPL N/AF

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP
TELEPHONE AMENDMENT - LABELING

Dear Sir or Madam:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to the FDA telephone contact on June 4, 2003 wherein FDA requested that Altana improve the readability of the submitted container and carton labeling.

This response has been identified as a TELEPHONE AMENDMENT to ANDA 65-024.

Please improve the readability and submit twelve final printed container and carton labeling pieces as a Telephone Amendment.

Altana has included twelve final printed labeling pieces for the 3.5 g container and carton with this submission.

If you require further information or clarification, please contact Ms. Audrey Zaweski, *Associate Director*, Regulatory Affairs at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RECEIVED
JUN 13 2003
OGD / CDER

RJA:jb

Dc: Michelle Dillahunt

\\Fsny\Users\Regulatory\Shared\Gentamicin\OphOintUSP0.3%.MinorLabelingAmdmt.061203.doc

Pharma

ALTANA

July 1, 2003

ALTANA Inc
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Neil J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

DRUG AMENDMENT
N/A S

VIA TELEFAX AND FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5 g
TELEPHONE AMENDMENT
RESPONSE TO MICROBIOLOGY CLARIFICATION

Dear Dr. Sweeney:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to the Minor Amendment submitted May 7, 2003 and to the teleconferences held between FDA and Altana representatives on June 20 and 26, 2003 regarding Microbiology clarifications.

This response has been identified as a TELEPHONE AMENDMENT to ANDA 65-024.

Each item has been addressed in **comment** / response format.

Microbiology Deficiencies:

1.

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ALTANA 7/1/2003 LETTER

JUL 14 2003

38. Chemistry Comments to be Provided to the Applicant

ANDA 65-024 APPLICANT: Altana, Inc.

DRUG PRODUCT: Gentamicin Sulfate Ophthalmic Ointment, USP 0.3%

The deficiencies presented below represent MINOR deficiencies.

A. Chemistry Deficiencies:

1.

2.

3.

Sincerely yours,

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

FAX Cover Sheet – Microbiology Deficiencies Enclosed

Office of Generic Drugs, CDER, FDA

Document Control Room, Metro Park North II

7500 Standish Place, Room 150

Rockville MD 20855-2773 (301-594-0320)

TO: Audrey Zaweski		**FROM:** Bonnie McNeal
Altana, Inc.		Microbiology Project Manager
PHONE: 631-454-7677 x3007		**PHONE:** (301) 827-0530
FAX: 631-756-5114		**FAX:** (301) 827-5911

Total number of pages, excluding this cover sheet: 8

Date: Oct. 29, 2003

Microbiology Deficiencies:

Enclosed are the microbiology deficiencies for ANDA 65-024. The submissions reviewed were submitted on May 7, June 13 and July 1, 2003. Please respond to this letter as soon as possible. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review. The response to this facsimile will be considered to represent a MINOR AMENDMENT and will be reviewed according to current OGD policies and procedures. The designation as a MINOR AMENDMENT-RESPONSE TO MICROBIOLOGY DEFICIENCIES should appear prominently in your cover letter.

Should you also have other outstanding deficiencies, for review purposes, please attempt to consolidate your responses into a single submission for this application.

If you have questions, feel free to call me.

Bonnie

BMc
10/29/03

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FDA 10/29/2003 FAX

Pharma

ALTANA

November 10, 2003

ORIG AMENDMENT

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Florence S. Fang
Director
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Food and Drug Administration
Document Control Room, Metro Park North II
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Rockville, MD 20855-2773

VIA FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5 g
MINOR AMENDMENT - RESPONSE TO CHEMISTRY DEFICIENCIES

Dear Dr. Fang:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to the Minor Amendment submitted May 7, 2003.

Altana Inc. acknowledges the FDA correspondence dated July 17, 2003 citing Chemistry comments:

This response has been identified as a MINOR AMENDMENT – RESPONSE TO CHEMISTRY DEFICIENCIES to ANDA 65-024.

Each item has been addressed in **comment** / response format.

Chemistry Deficiencies:

1.

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ALTANA 11/10/2003 LETTER

Pharma

ALTANA

ORIGINAL

December 15, 2003

Neal J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/A 3

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www.altanainc.com

VIA FEDERAL EXPRESS

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
MINOR AMENDMENT-RESPONSE TO MICROBIOLOGY DEFICIENCIES

Dear Mr. Sweeney:
Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to Amendment submitted May 7, 2003 and July 1 2003.

Altana Inc. acknowledges the following FDA correspondence dated October 29, 2003

Each item has been addressed in **comment** / response format.

A. Microbiology Deficiencies:

1.

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ALTANA 12/15/2003 LETTER

Altana acknowledges the reviewer's comment regarding effective review of future submissions.

If you require further information or clarification, please contact Audrey Zaweski, Associate Director Regulatory Affairs, at (631) 454-7677 extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:ca

Attachments

6.1

Pharma

ALTANA

January 21, 2004

ALTANA Inc
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Neil J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/AS

VIA TELEFAX AND FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5 g
TELEPHONE AMENDMENT
RESPONSE TO MICROBIOLOGY - CLARIFICATION

Dear Dr. Sweeney:

Reference is made to our Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

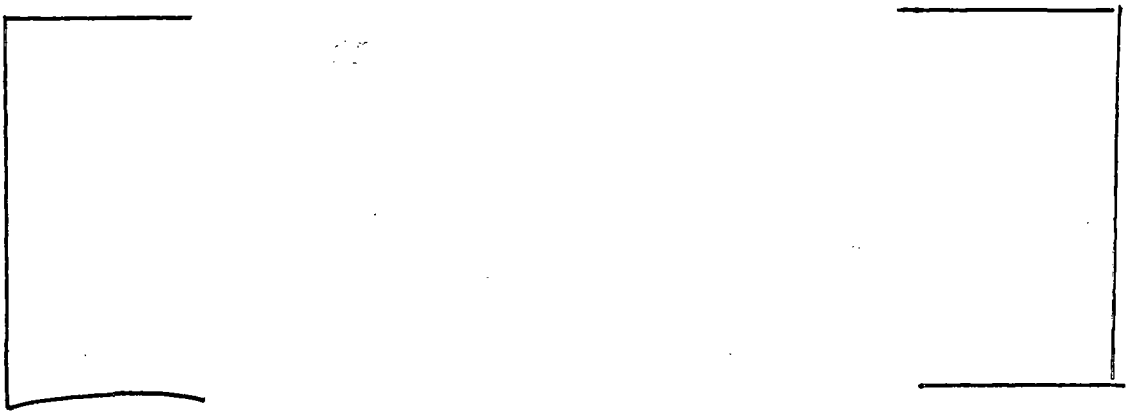
Reference is also made to the Minor Amendment submitted December 15, 2003 and to the teleconference held between FDA and Altana representatives on January 13, 2004 requesting clarification of information provided in the Minor Amendment.

This response has been identified as a TELEPHONE AMENDMENT to ANDA 65-024.

Each item has been addressed in **comment** / response format.

1.

2.



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If you require further information or clarification, please contact Ms. Audrey Zaweski, Associate Director, Regulatory Affairs at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:ca

MAR -1 2004

38. Chemistry Comments to be Provided to the Applicant

ANDA 65-024 APPLICANT: Altana, Inc.

DRUG PRODUCT: Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%

The deficiencies presented below represent MINOR deficiencies.

A. Chemistry Deficiencies:

1. We note from the submitted [redacted] Please comment.

   Please provide comparative data on [redacted] between your product and the RLD Garamycin.

2. Please respond to the attached deficiencies regarding sterility assurance issues.

Sincerely yours,

R.C. adams for

Vilayat S. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research

H. LIST OF MICROBIOLOGY DEFICIENCIES AND COMMENTS

ANDA: 65-024 APPLICANT: Altana Inc.

DRUG PRODUCT: Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%

A. Microbiology Deficiencies:

1.

2.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

1. [redacted]

Please clearly identify your amendment to this facsimile as "RESPONSE TO MICROBIOLOGY DEFICIENCIES". The "RESPONSE TO MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,

Neal J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research

Pharma

ALTANA

April 2, 2004

ALTANA Inc
60 Baylis Road
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Vilayat S. Sayeed, Ph.D.
Director
Division of Chemistry III
Neil J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA 65-024

ORIG AMENDMENT

VIA FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5 g
MINOR AMENDMENT-RESPONSE TO CHEMISTRY AND MICROBIOLOGY DEFICIENCIES

Dear Drs. Sayeed and .Sweeney:

Reference is made to the Altana Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g. Reference is also made to the March 1, 2004 FDA correspondence citing Chemistry and Microbiology comments. This response has been identified as a MINOR AMENDMENT to ANDA 65-024. Each item has been addressed in **comment** / response format.

A. Chemistry Deficiencies

[redacted]

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ALTANA 4/2/2004 LETTER

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6.1

Pharma

ALTANA

May 7, 2004

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ORIG AMENDMENT
N/AM

Vilayat S. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

VIA TELEFAX (301) 594-1174 AND FEDERAL EXPRESS

ANDA 65-024
GENTAMICIN SULFATE OPTHALMIC OINTMENT USP, 3.5 g
TELEPHONE AMENDMENT

Dear Dr. Sayeed:

Reference is made to the Altana Abbreviated New Drug Application dated August 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Ophthalmic Ointment USP, 3.5g.

Reference is also made to the Altana Minor Amendment submitted April 2, 2004 and the May 4, 2004 FDA Telephone Request for information regarding comparative data between the RLD, Garamycin and the Altana drug product.

At the time that development work was initiated for Gentamicin Sulfate Ophthalmic Ointment USP, ——— testing of the RLD, Garamycin, was not performed. Subsequent attempts by Altana to purchase the RLD have been unsuccessful as Garamycin is no longer commercially available.

If you require further information or clarification, please contact Ms. Audrey Zaweski, Associate Director, Regulatory Affairs at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RECEIVED
MAY 10 2004
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RJA:ca

Pharma

ALTANA

June 28, 2004

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ORIG AMENDMENT
N/AS

Neal J. Sweeney, Ph.D.
Microbiology Team Leader
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place,
Rockville, MD 20855-2773

VIA TELEFAX (301) 827-5911 AND FEDERAL EXPRESS

ANDA 65-024
Gentamicin Sulfate Opthalmic Ointment USP, 0.3%
AMENDMENT - RESPONSE TO MICROBIOLOGY DEFICIENCIES

Dear Mr. Sweeney:
Reference is made to our Abbreviated New Drug Application dated August 4, 1998 submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Gentamicin Sulfate Opthalmic Ointment USP, 0.3%.

Altana Inc. acknowledges the FDA correspondence dated May 28, 2004 citing microbiology deficiencies.

In lieu of responding to each comment listed for Section A of this correspondence, Altana has prepared an overall summary of the ———————— throughout the manufacturing process. A separate response has been provided for Section B.

A. Microbiology Deficiencies:

1.

JUN 29 2004
OGD / CDER

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ALTANA 6/28/2004 LETTER

If you require further information or clarification, please contact Audrey Zaweski, Associate Director Regulatory Affairs, at (631) 454-7677 extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski for

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

RJA:ca

Attachments

Pharma

ALTANA

July 30, 2004

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NC

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place
Rockville, MD 20855

VIA TELEFAX (301) 594-0183 AND FEDERAL EXPRESS

ANDA 65-024
Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%
TELEPHONE AMENDMENT

Dear Mr. Buehler:

Reference is made to the Altana Inc. Abbreviated New Drug Application Gentamicin Sulfate Ophthalmic Ointment USP, 0.3%, submitted August 4, 1998 pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to the July 30, 2004 FDA Telephone Contact requesting that Altana Inc. revise its Basis For Submission from Garamycin® (gentamicin sulfate ophthalmic ointment), (N50425 Schering Corporation), to Gentak® (Gentamicin Sulfate Opthalmic Ointment USP, 0.3%), (ANDA 64-093), (Akorn Inc.).

As requested, Altana Inc. has revised the Basis for ANDA Submission statement to reflect the change in the Reference Listed Drug. Copies of the revised statement and the reference page from the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, 24th Edition (p. 3-176) have been included with this telefax.

If you require further information or clarification, please contact Audrey Zaweski, Associate Director Regulatory Affairs, at (631) 454-7677 extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely

ALTANA INC.

Audrey Zaweski for,
Robert J. Anderson, Esq.
Senior Director, Scientific Affairs

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Attachments

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