

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-422

ADMINISTRATIVE DOCUMENTS

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE : July 3, 2002

TO : Director
Division of Bioequivalence (HFD-650)

FROM : Chief, Regulatory Support Branch
Office of Generic Drugs (HFD-615)  03-JUL-2002

SUBJECT: Examination of the Bioequivalence Clinical study submitted with an ANDA for Ciclopirox Olamine Topical Suspension USP, 0.77% to determine if the application is substantially complete for filing.

Altana Inc. has submitted ANDA 76-422 for Ciclopirox Olamine Topical Suspension USP, 0.77%. The ANDA contains a first generic. In order to accept an ANDA that contains a first generic, the Agency must formally review and make a determination that the application is substantially complete. Included in this review is a determination that the Bioequivalence study is complete, and could establish that the product is bioequivalent.

Please evaluate whether the Clinical Study submitted by Altana on May 28, 2002 for its Ciclopirox Olamine product satisfies the statutory requirements of "completeness" so that the ANDA may be filed.

A "complete" bioavailability or bioequivalence study is defined as one that conforms with an appropriate FDA guidance or is reasonable in design and purports to demonstrate that the proposed drug is bioequivalent to the "listed drug".

In determining whether a bio study is "complete" to satisfy statutory requirements, the following items are examined:

1. Study design
 - (a) Appropriate number of subjects
 - (b) Description of methodology

2. Study results
 - (a) Individual and mean data is provided
 - (b) Individual demographic data
 - (c) Clinical summary

The issue raised in the current situation revolves around whether the study can purport to demonstrate bioequivalence to the listed drug.

We would appreciate a cursory review and your answers to the above questions as soon as possible so we may take action on this application.

**APPEARS THIS WAY
ON ORIGINAL**

BIOEQUIVALENCE CHECKLIST FOR APPLICATION COMPLETENESS
First Generic ANDA

ANDA# 76-422 FIRM NAME Altana, Inc.

DRUG NAME Ciclopirox Olamine Topical Suspension, 0.77% (w/w)

DOSAGE FORM Lotion

Requested by: Greg Davis
Chief, Regulatory Support Team, (HFD-615)

Summary of Findings by Division of Bioequivalence

Study meets statutory requirements

Study does NOT meet statutory requirements

Reason: Exhibit lot #'s for test does not match clinical lot #'s & no data diskettes were submitted.

Waiver meets statutory requirements

Waiver does NOT meet statutory requirements

Reason:

RECOMMENDATION: COMPLETE INCOMPLETE

Reviewed by:

Reviewer James E. Chaney Date: 7/29/2002
James E. Chdney

Team Leader [Signature] Date: 7/31/2002

Dale P. Conner [Signature] Date: 7/31/02
Director, Division of Bioequivalence

Item Verified:	Yes	No	Required Amount	Amount Sent	Comments
Protocol	X				pp 169-208
Assay Methodology		X			NA No drug analysis - clinical endpoint
Procedure SOP		X			NA
Methods Validation		X			NA
Study Results Ln/Lin		X			NA
Adverse Events	X				pp 1067-1106
IRB Approval	X				
Dissolution Data					NA
Pre-screening of Patients	X				Inclusion/ Exclusion criteria, pp137-8
Chromatograms		X			NA
Consent Forms	X				Pg 222
Composition	X				Pages 60, 63, 73, 84 & 1151. Inactive ingredients conform to IIG.
Summary of Study	X				See synopsis, pp 128-134
Individual Data & Graphs, Linear & Ln	X				Individual data is presented.
PK/PD Data Disk (or Elec Subm)		X			Firm should submit data disks.
Randomization Schedule	X				pp376-391
Protocol Deviations	X				p148
Clinical Site	X				CRO - _____ - 14 study sites listed on pp 228-229
Analytical Site		X			Not applicable. Clinical endpoints
Study Investigators	X				CV's, pp230-375
Medical Records	X				
Clinical Raw Data	X				
Test Article Inventory	X				

BIO Batch Size					* See asterisked note under "Additional Comments regarding the ANDA"
Assay of Active Content Drug		X	Test & Reference should have	Submitted only assay of reference	* See asterisked note under "Additional Comments regarding the ANDA"
Content Uniformity		X			
Date of Manufacture					* See asterisked note under "Additional Comments regarding the ANDA"
Exp. Date of RLD	X				The RLD (Medicis' Loprox® Lotion) expired March 2002. p102
BioStudy Lot Numbers	X				* See asterisked note under "Additional Comments regarding the ANDA"
Statistics	X				pp155-6
Summary results provided by the firm indicate studies pass BE criteria	X				p155
Waiver requests for other strengths / supporting data		X			NA - No waiver requests

Additional Comments regarding the ANDA:

*1.The lot numbers on the exhibit batch records for the active test product and placebo do not match the corresponding lot numbers presented in the clinical report. Therefore, we do not know the characteristics such as batch size, assay and date of manufacture of the batch used in the clinical study.

2. No data diskettes were submitted. Regarding data diskettes for antifungals, the attachment to this review should be forwarded to the firm.

3. On October 31, 2000 the firm submitted a protocol as part of IND 15-328 on this drug product. The protocol was reviewed by Mary Fanning, M.D., of OGD on January 8, 2001. She recommended that it should be accepted and that the following should be communicated to the sponsor: "Trichophyton rubrum is the most common infecting organism. Therefore, >50% of the subjects should have fungal cultures positive for T. rubrum." OGD sent this recommendation as part of its response to the IND. In the current ANDA the firm has incorporated the recommendation into its clinical study (p 151).

The protocol was designed based on the FDA Draft Guidance for the Performance of a Bioequivalence Study for Topical Antifungal Products (Feb 1990). The study objective was to evaluate the safety and therapeutic equivalence of Altana, Inc.'s Ciclopirox Olamine Lotion, 1% to the RLD and its efficacy over its vehicle (placebo) in the treatment of interdigital tinea pedis.

**ATTACHMENT TO REVIEW OF COMPLETENESS FOR FILING
ANDA 76-422 FROM ALTANA ON ITS CICLOPIROX LOTION**

The following information should be included on a disk or CD:

1. A list of file names included in the CD or diskette(s) with a simple description of the content of each file. A document file containing a description of each dataset and an explanation of the variables included in each of the SAS datasets.

All SAS transport files should use .xpt as the file extension and should not be compressed.

The SAS program to open the transport files and the SAS program for decode format for each SAS variable should be included.

2. The sponsor should identify and provide the list of subjects who are included and excluded from each population analysis separately. The variable(s) derived for analysis should include specific data such as treatment per subject, analysis populations (e.g., intend-to-treat (ITT); modified intend-to-treat (MITT); per protocol (PP); evaluable population (EVP)), clinical cure/fail, mycological cure/fail and total cure/fail, etc. The sponsor should also provide the reason(s) for exclusion of subjects from the (M) ITT, evaluable population (PP), and other population(s) used for analysis by the firm. These variables could be included in a single SAS transport file.
3. SAS transport file(s) – covering all variables collected in the Case Report Forms (CRFs) per patient. The sponsor should provide a single file for each dataset such as demographics, baseline admission criteria, baseline vital signs, dermatological examination per each visit with visit date, adverse event, reasons for discontinuation of treatment, medical history, compliance and comments, etc.
4. The methods used to derive the variables should be included and explained.

**APPEARS THIS WAY
ON ORIGINAL**

RECORD OF TELEPHONE CONVERSATION

<p>On this date, we contacted Altana, Inc (Altana) in response to their fax dated November 19, 2002, which requests for clarification of our correspondences dated October 23, 2002 for ANDA 76-422 and 76-435.</p> <p>Deficiency #4 (ANDA 76-442) Firm's comment: Is there a test in the USP or other reference? FDA's response: No. Please use your own judgement in developing a _____ test.</p> <p>Deficiency #5 (ANDA 76-442) and #4 (ANDA 76-435) Firm's comment: Are you referring to the drug product specifications? FDA's response: We are referring to the validation of your experiment. What are the limits that you are checking in your validation? (e.g. limit of detection and quantitation)</p> <p>Ms. Andersen thanked us for our time.</p>	<p align="center">DATE: 12/19/02</p>
	<p align="center">ANDA NUMBER 76-422 & 76-435</p>
	<p align="center">TELECON INITIATED BY FIRM</p>
	<p align="center">PRODUCT NAME: Ciclopirox Olamine Topical Suspension USP, 0.77% (ANDA 76-442) and Ciclopirox Olamine Cream USP, 0.77% (ANDA 76-435)</p>
	<p align="center">FIRM NAME: Altana, Inc.</p>
	<p align="center">FIRM REPRESENTATIVES: Cynthia Andersen</p>
	<p align="center">TELEPHONE NUMBER: 631-454-7677 ext. 2093</p>
	<p align="center">FDA REPRESENTATIVES Liang Lii Huang James Fan Sarah Ho</p>
	<p align="center">SIGNATURES: L.Huang <i>L. Huang</i> 12/21/02 J.Fan <i>J. Fan</i> 12/21/02 S.Ho <i>S. Ho</i> 12/26/02</p>

Orig: ANDA 76-442
ANDA 76-435
Cc: Division File
Chem. I Telecon Binder
V:\FIRMSAM\ALTANA\TELECONS\76422.02.12.19.doc

RECORD OF TELEPHONE CONVERSATION

<p>This call was initiated by the Agency to request for tightening of the _____ specification.</p> <p>Agency: In your 5/30/03 minor amendment, your _____ specifications remain too high. All of your _____ especially the _____</p> <p>Firm: You mean the _____?</p> <p>Agency: Yes, we also meant the _____ the _____ Your specifications for the _____ are too high _____ You need to revise based on your data or provide justification by testing RLD at expiry or near expiry.</p> <p>Firm: Understood, we will revise. How should we submit this? As a t-amendment?</p> <p>Agency: Yes, you have 10 days to submit your t-amend.</p>	<p>DATE: 9/30/03</p> <p>ANDA NUMBER 76-422</p> <p>TELECON INITIATED BY Agency</p> <p>PRODUCT NAME Ciclopirox Suspension</p> <p>FIRM NAME: Altana Inc.</p> <p>FIRM REPRESENTATIVES: Audrey Zaweski, Weldon Probe, Carey Keave, Eric Faldor</p> <p>TELEPHONE NUMBER: 631-454-7677 ext. 3007</p> <p>FDA REPRESENTATIVES Jim Fan, Liang-Lii Huang, Jim Fan</p> <p>SIGNATURES: Jim Fan  9/30/03 Liang-Lii Huang  Ann Vu </p>
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Orig: 76-422

Cc: Division File

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-422

CORRESPONDENCE

May 28, 2002

VIA FEDERAL EXPRESS

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

Refused to receive.
25 JUL 2002
Sugony D. Davis

Original Submission
Abbreviated New Drug Application
Ciclopirox Lotion 0.77% (w/w)
(Ciclopirox Olamine Topical Suspension USP)

Dear Sir or Madam:

Pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with the provisions under 21 CFR §314.94, Altana Inc. is submitting this Abbreviated New Drug Application to market a new drug, **Ciclopirox Lotion 0.77% (w/w) (Ciclopirox Olamine Topical Suspension USP)**.

The Reference Listed Drug (RLD) that is the basis for this submission is, **LOPROX® LOTION (ciclopirox) 0.77% (w/w)** – Manufactured for Medicis, The Dermatology Company® by West Pharmaceutical Services, NDA 19-824. The proposed drug, Ciclopirox Lotion 0.77% (w/w) (Ciclopirox Olamine Topical Suspension USP) contains the same active ingredient and is identical in strength, dosage form and route of administration to the RLD. All inactive ingredient amounts conform to the ranges as listed in the Inactive Ingredient Guide (January 1996).

The exhibit batch, Batch #E800, included in this application was fully packaged utilizing the 30 and 60 mL presentations for which approval is currently requested. The number of units filled for these packaging sizes and the disposition of any remaining bulk product are reconciled in the exhibit batch record.

Included in this six (6) volume submission, along with Form FDA 356, is the required Patent Status and Exclusivity Statements; Draft Labeling; Bioequivalence Study; full Components and Composition statements; Raw Materials Controls, description of the Manufacturing Facilities, Manufacturing and Processing Instructions, In-Process Controls, Filling and Packaging procedures; Container/Closure System; controls for the Finished Dosage Form, Analytical Methods; Stability of the Finished Dosage Form; Environmental Assessment and Certification Requirements of the Generic Drug Enforcement Act of 1992.

RECEIVED

MAY 29 2002

OGD / CDER

Original Submission
Abbreviated New Drug Application
Ciclopirox Lotion 0.77% (w/w)
(Ciclopirox Olamine Topical Suspension USP)

May 28, 2002
Page 2

All regulatory correspondence related to this Abbreviated New Drug Application should be addressed to the following:

Ms. Audrey Bialeski
Manager, Regulatory Affairs
Altana, Inc.
60 Baylis Road
Melville, NY 11747
Telephone: (631) 454-7677 X 3007
Facsimile: (631) 756-5114

A certified copy of the technical section and a copy of the Methods Validation package, are being sent to the New York District Office under separate cover.

We trust that this submission will meet your approval. Please advise if you require any additional information.

Sincerely,
ALTANA INC.

Handwritten signature of Audrey Bialeski in cursive script, with a small flourish at the end.

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

RJA/ap

Enclosures

ANDA 76-422

JUL 25 2002

Altana Inc.
Attention: Robert J. Anderson
60 Baylis Road
Melville, NY 11747
lullllllllllllllllllll

Dear Sir:

Please refer to your abbreviated new drug application (ANDA) dated May 28, 2002 submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Olamine Topical Suspension USP, 0.77%.

We have given your application a preliminary review, and we find that it is not sufficiently complete to merit a critical technical review.

We are refusing to receive this ANDA under 21 CFR 314.101(d)(3) for the following reasons:

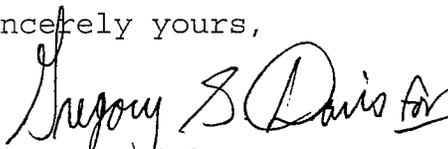
It appears that the batch you have manufactured to support bioequivalence (lot C660) is not the same batch manufactured to support approval of your ANDA (lot E800). Each ANDA must have a dedicated test batch manufactured specifically to support approval of the ANDA. This **same** test batch must be used for the chemistry, manufacturing and controls of the proposed drug product, for the required bioequivalence data, *in vitro* and *in vivo*, and the stability studies.

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

Upon receipt of this communication, you may either amend your application to correct the deficiencies or withdraw your application under 21 CFR 314.99. If you have any questions please call:

Beth Fritsch
Project Manager
(301) 827-5862

Sincerely yours,



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

ANDA 76-422

cc: DUP/Jacket

Division File

HFD-92

Field Copy

HFD-610/R.West

HFD-610/P.Rickman

HFD-615/MBennett

Endorsement: HFD-615/GDavis, Chief, RSB *Davis* 25-Jul-2002 date

HFD-615/BFritsch, CSO *Ben Fritsch* 7/25/02 date

Word File

V:/FIRMSAM/altana/ltrs&rev/76422.rtf

F/T File

ANDA Refuse to Receive!

**APPEARS THIS WAY
ON ORIGINAL**

August 5, 2002

William Peter Rickman
Acting Director
Division of Labeling and Program Support
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 Federal Express/Fax

NEW CORRESP

NC TO FAX

WAI
R
6/5/02

ANDA 76-422
Ciclopirox Olamine Topical Suspension USP, 0.77%
Response to "Refuse to Receive" letter

Dear Mr. Rickman:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Ciclopirox Olamine Topical Suspension USP, 0.77% submitted May 28, 2002 pursuant to Section 505(j) of the Federal Food Drug and Cosmetic Act.

Reference is also made to the Office of Generic Drugs "Refuse to Receive" letter of July 25, 2002, as well as several telephone conferences between Ms. Audrey Bialeski of Altana Inc. and several representatives of the Office of Generic Drugs, Ms. Beth Fritsch, and Lt. Gregory Davis on August 1 and 2, 2002.

The administration's comment was:

"It appears that the batch you have manufactured to support bioequivalence (lot C660) is not the same batch manufactured to support approval of your ANDA (lot E800). Each ANDA must have a dedicated test batch manufactured specifically to support approval of the ANDA. This same test batch must be used for the chemistry, manufacturing and controls of the proposed drug product, for the required bioequivalence data, *in vitro* and *in vivo*, and the stability studies.

Thus, it will not be received as an abbreviated new drug application within the meaning of Section 505(j) of the Act.

As explained to the Office's representatives the lot numbers cited in the bioequivalence report were incorrect. The Clinical Research Organization that performed this study inadvertently used the lot numbers from the previous report that they had performed for us, Econazole Nitrate Cream (ANDA 76-075).

RECEIVED

AUG 06 2002

OGD / CDER

Ciclopirox Olamine Topical Suspension USP, 0.77%

Lt. Davis reviewed the Econazole Nitrate Cream biostudy report and ascertained that the lot numbers cited in the Ciclopirox Olamine Topical Suspension study were indeed those of the Econazole Nitrate Cream study.

Therefore, as per Lt. Davis's instructions, Altana Inc. is herein enclosing the corrected report for Ciclopirox Olamine Topical Suspension USP, 0.77%.

If any further information is required please contact Ms. Audrey Bialeski at (631) 454-7677 Ext. 3007.

Sincerely
ALTANA INC.



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

RJA/ap

Enclosures

NEW CORRESP
NC

ALTANA

TELEFAX DATED: August 8, 2002

Altana Inc. 60 Baylis Road, Melville, NY 11747 631-454-7677 Fax: 631-756-5114

ALTANA PHARMA GROUP

TO: Beth Fritsch

FAX NO: 301-594-1174

FROM: Audrey Bialeski

OF PAGES (including this page): 5

This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

ANDA 76-422

Ciclopirox Olamine Lotion 0.77%

(Ciclopirox Olamine Topical Suspension USP 0.77%)

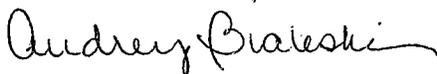
Dear Beth:

As discussed in our conference call this morning, please find the following items included with this telefax:

- A revised Form FDA 356h for the original ANDA submission dated 5/28/02 with the correct NDA holder identified as Medicis, The Dermatology Company.
- A current Form FDA 356h for today's Amendment dated August 8, 2002.

Please contact me at (631) 454-7677 extension 3007 if you require any additional information. A hard copy of this submission will be forwarded via Federal Express for delivery tomorrow morning, Friday, August 9, 2002.

Sincerely,



Audrey Bialeski
Manager, Regulatory Affairs

AB

RECEIVED
AUG 09 2002
OGD / CDER



ANDA 76-422

AUG - 8 2002

Altana Inc.
Attention: Robert J. Anderson
60 Baylis Road
Melville, NY 11747
lulllulllulllulllulll

Dear Sir:

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 our "Refuse to Receive" letter dated July 25, 2002 and your amendment dated August 5, 2002.

NAME OF DRUG: Ciclopirox Olamine Topical Suspension USP, 0.77%

DATE OF APPLICATION: May 28, 2002

DATE (RECEIVED) ACCEPTABLE FOR FILING: August 6, 2002

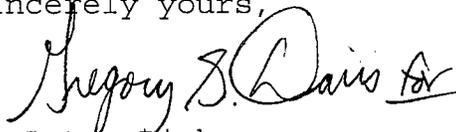
We will correspond with you further after we have had the opportunity to review your application.

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

Should you have questions concerning this application contact:

Sarah Ho
Project Manager
(301) 827-5848

Sincerely yours,



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

ANDA 76-422

cc: DUP/Jacket
Division File
HFD-82
Field Copy
HFD-330
HFD-610/R.West
HFD-610/P.Rickman
HFD-615/MBennett

Endorsements: HFD-615/GDavis, Chief, RSB *GDavis 08 AUG 2002* date
HFD-615/BFritsch, CSO *Bob Fritsch 8/7/02* date
Word Document
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F/T by
ANDA Acknowledgment Letter!

*2.1

Pharma



September 18, 2002

Off
9/23/02
BIOAVAILABILITY
NEW CORRESP
NC

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

ALTANA Inc
60 Baylis Road
Melville, NY 11747
USA
T +1 (631) 454-7677
www.altanainc.com

VIA FEDERAL EXPRESS

ANDA 76-422
CICLOPIROX OLAMINE LOTION
(CICLOPIROX OLAMINE TOPICAL SUSPENSION USP, 0.77%)
NEW CORRESPONDENCE BIOEQUIVALENCE

Dear Sir or Madam:

Reference is made to the Altana Inc. Abbreviated New Drug Application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Olamine Lotion (Ciclopirox Olamine Topical Suspension USP, 0.77%) and accepted for filing on August 6, 2002.

Altana Inc. is hereby submitting the data diskettes for the bioequivalence study conducted to support the ANDA submission.

If you have any questions or require additional information, please contact Ms. Audrey Bialeski, Manager, Regulatory Affairs, at (631) 454-7677, extension 3007. Fax communication may be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Bialeski for

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

RJA:tw

Enc.

RECEIVED

SEP 19 2002

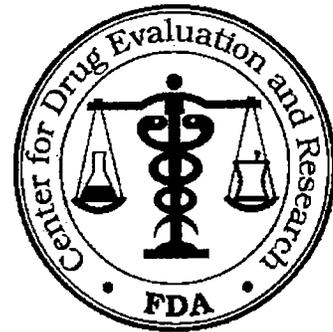
OGD / CDER

MINOR AMENDMENT

ANDA 76-422

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)

OCT 23 2002



TO: APPLICANT: Altana Inc.

TEL: 631-454-7677 ext. 3007

ATTN: Audrey Bialeski

FAX: 631-756-5114

FROM: Sarah Ho

PROJECT MANAGER: 301-827-5754

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ciclopirox Olamine Topical Suspension USP, 0.77%.

Reference is also made to your amendment(s) dated: August 5, 2002.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (3 pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. 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 should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:

CMC comments provided.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

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JMS
10/23/02

Redacted 2 page(s)

of trade secret and/or

confidential commercial

information from

FDA FAX 10/23/2002

3. Information related to labeling and bioequivalency is pending review. After the reviews are completed, any deficiencies found will be communicated to you under separate covers.
4. The firms referenced in your ANDA application relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval.

Sincerely yours,



Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

November 19, 2002

Sarah Ho, Project Manager
Division of Chemistry I
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

VIA FACSIMILE

ANDA 76-422

Ciclopirox Olamine Topical Suspension USP, 0.77%

ANDA 76-435

Ciclopirox Olamine Cream USP, 0.77%

REQUEST FOR CLARIFICATION

Dear Ms. Ho:

Reference is made to the Altana Inc. Abbreviated New Drug Applications for Ciclopirox Olamine Topical Suspension USP, 0.77% and Ciclopirox Olamine Cream USP, 0.77%, dated May 28, 2002 and June 28, 2002, respectively, submitted in accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Reference is also made to the FDA deficiency letters dated October 23, 2002 regarding ANDA 76-422 and ANDA 76-435. In order to appropriately respond to these deficiencies, Altana is requesting clarification of the following comments:

Ciclopirox Olamine Topical Suspension USP, 0.77%

4. Please include a _____ test for the drug product release and stability.

Altana is requesting that the reviewer cite the reference for the _____ test.

5. Please include the _____
_____ of the drug product.

The _____ are provided in the drug product specifications. Are these the _____ that are being referred to in the above comment?

ANDA 76-422
Ciclopirox Olamine Topical Suspension USP, 0.77%
ANDA 76-435
Ciclopirox Olamine Cream USP, 0.77%
REQUEST FOR CLARIFICATION
November 26, 2002
Page 2 of 3

Ciclopirox Olamine Cream USP, 0.77%

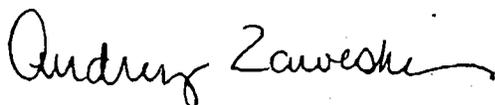
4. Please provide the _____
_____ of the drug product.

The _____ are provided in the drug product specifications. Are these the
_____ that are being referred to in the above comment?

If you require additional information, please contact me at (631) 454-7677 extension 3007 or Ms. Cynthia Andersen at extension 2093. FAX communications can be made to (631) 756-5114.

Sincerely,

ALTANA INC.



Audrey Zaweski
Manager, Regulatory Affairs

AZ:ca

Pharma



ORIG AMENDMENT
N/A

ALTANA Inc
60 Baylis Road
Melville, NY 11747
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T +1 (631) 454-7677
www.altanainc.com

December 20, 2002

Rashmikant M. Patel, Ph.D.
Director, Chemistry I
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

VIA FEDERAL EXPRESS

ANDA 76-422
CICLOPIROX LOTION 0.77%
(CICLOPIROX OLAMINE TOPICAL SUSPENSION USP, 0.77%)
MINOR AMENDMENT

Dear Dr. Patel:

Reference is made to the Abbreviated New Drug Application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Olamine Topical Suspension USP, 0.77%.

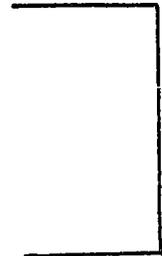
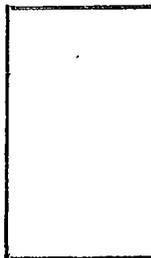
Altana Inc. acknowledges the following FDA correspondence dated October 23, 2002 stating Altana's application is deficient, and, therefore, Not Approvable under Section 505 of the Act. The Division of Chemistry comments noted in the aforementioned correspondence have been addressed as follows:

This response has been identified as a MINOR AMENDMENT to ANDA 76-422.

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

A. Deficiencies:

1.



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DEC 23 2002

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information from

ALTANA 12/20/02 LETTER

ANDA 76-422
Ciclopirox Lotion 0.77%
(Ciclopirox Olamine Topical Suspension USP, 0.77%)
MINOR AMENDMENT
December 20, 2002
Page 6 of 6

4. The firms referenced in your ANDA application relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval.

Altana acknowledges that the firms referenced in the ANDA application relative to the manufacturing and testing of the product must be in compliance with cGMP's at the time of approval.

If you require further information or clarification, please contact Ms. Audrey Zaweski, Manager, 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

RJA:ca

Attachments

Pharma



April 24, 2003

ORIG AMENDMENT

N/AB

Dale Conner, Pharm. D.
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
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VIA FEDERAL EXPRESS

ANDA 76-422

**Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP, 0.77%)
BIOEQUIVALENCE AMENDMENT**

Dear Dr. Conner:

Reference is made to the Abbreviated New Drug Application dated May 28, 2002 submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP, 0.77%).

This Amendment contains a re-organization of the clinical study data analysis used to support the bioequivalence of the Altana product. The data analysis was re-organized in accordance with recommendations Altana has received from the Division of Bioequivalence for several other ANDA submissions. This information is provided in an effort to better facilitate the review of the application.

Altana requests that the Division of Bioequivalence conduct its review of the bioequivalence of the Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP, 0.77%) using the clinical study report and associated data files contained in this submission.

If you have any questions or require additional information please contact Ms. Audrey Zaweski, *Associate Director*, Regulatory Affairs at (631) 454-7677 ext. 3007. Fax communications can be made to (631) 756-5114.

Sincerely,

ALTANA INC.

Audrey Zaweski ^{for}

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

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APR 25 2003

OGD / CDER

RJA:ic

MINOR AMENDMENT

ANDA 76-422

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)



MAY - 1 2003

APPLICANT: Altana Inc.

TEL: 631-454-7677 ext 3007

ATTN: Audrey Zaweski

FAX: 631-756-5114

FROM: Thuyanh Vu

PROJECT MANAGER: 301-827-5754

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP).

Reference is also made to your amendment(s) dated: December 20, 2002.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (2 pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. 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 should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:

CDC comments enclosed.

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If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

W 5/1/03

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information from

FDA FAX 5/1/2003

Pharma



May 20, 2003

Rashmikant M. Patel, Ph.D.
Director, Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
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VIA FEDERAL EXPRESS

ANDA 76-422

Ciclopirox Lotion 0.77%

(Ciclopirox Olamine Topical Suspension USP, 0.77%)

MINOR AMENDMENT

~~MINOR AMENDMENT~~

N/AM

Dear Dr. Patel:

Reference is made to the Abbreviated New Drug Application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP, 0.77%).

Altana Inc. acknowledges the FDA correspondence dated May 1, 2003 stating Altana's application is deficient, and, therefore, Not Approvable under Section 505 of the Act. The Division of Chemistry comments noted in the aforementioned correspondence have been addressed as follows:

This response has been identified as a MINOR AMENDMENT. Each item has been addressed in **comment / response** format.

A. Deficiencies:

✓ 1.



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MAY 21 2003

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confidential commercial

information from

ALTANA 5/20/2003 LETTER

Pharma



October 9, 2003

Rashmikant M. Patel, Ph.D.
Director, Chemistry I
Office of Generic Drugs
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Food and Drug Administration
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altana.com

~~GEN AMENDMENT~~

VIA FACIMILE/FEDERAL EXPRESS

ANDA 76-422
Ciclopirox Lotion 0.77%
(Ciclopirox Olamine Topical Suspension USP, 0.77%)
TELEPHONE AMENDMENT

ORIG AMENDMENT
N/A/M

Dear Dr. Patel:

Reference is made to the Abbreviated New Drug Application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act for Ciclopirox Lotion 0.77% (Ciclopirox Olamine Topical Suspension USP, 0.77%).

Reference is also made to the teleconference held on September 20, 2003 between Altana Inc. and FDA representatives, requesting that Altana clarify the _____ specifications for the drug product.

Altana has reviewed the stability data acquired to date and has revised the limits for the degradation products of Ciclopirox Olamine.

The changes for the In-Process, Finished Product and Stability Specifications are summarized below; copies have been included with this correspondence:

	In-Process	Finished Product	Stability
 			

OCT 10 2003

MW
10/10

ANDA 76-422

CICLOPIROX LOTION 0.77%

(CICLOPIROX OLAMINE TOPICAL SUSPENSION USP, 0.77%)

TELEPHONE AMENDMENT

October 9, 2003

Page 2 of 2

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

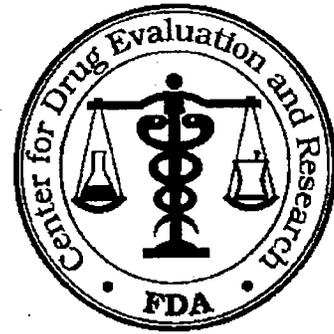
RJA:ic

Attachments

MINOR AMENDMENT

ANDA 76-422

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)



JAN 16 2004

APPLICANT: Altana, Inc.

TEL: 631-454-7677 ext. 3007

ATTN: Audrey Zaweski

FAX: 631-756-5114

FROM: Thuyanh Vu

PROJECT MANAGER: 301-827-5754

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated May 28, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ciclopirox Topical Suspension USP, 0.77% (Lotion).

Reference is also made to your amendment(s) dated: May 20 and October 9, 2003.

The application is deficient and, therefore, Not Approvable under Section 505 of the Act for the reasons provided in the attachments (1 pages). This facsimile is to be regarded as an official FDA communication and unless requested, a hard copy will not be mailed.

The file on this application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the application. Your amendment should respond to all of the deficiencies listed. Facsimiles or partial replies will not be considered for review, nor will the review clock be reactivated until all deficiencies have been addressed. 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 should appear prominently in your cover letter. You have been/will be notified in a separate communication from our Division of Bioequivalence of any deficiencies identified during our review of your bioequivalence data. If you have substantial disagreement with our reasons for not approving this application, you may request an opportunity for a hearing.

SPECIAL INSTRUCTIONS:

CMC comments enclosed

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, OR PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If received by someone other than the addressee or a person authorized to deliver this document to the addressee, you are hereby notified that any disclosure, dissemination, copying, or other action to the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us by mail at the above address.

W 1/16/04

36. CHEMISTRY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 76-422

APPLICANT: Altana, Inc.

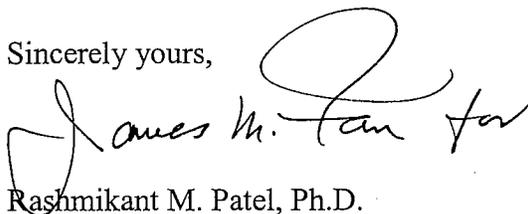
DRUG PRODUCT: Ciclopirox Olamine Topical Suspension USP, 0.77%

The deficiency presented below represents a MINOR deficiency.

A. Deficiency:

Labeling deficiencies were communicated to you via facsimile on December 31, 2003. You should address the issues in the December 31 communication prior to or concurrent with your response to this communication.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Rashmikant M. Patel" followed by a flourish.

Rashmikant M. Patel, Ph.D.

Director

Division of Chemistry I

Office of Generic Drugs

Center for Drug Evaluation and Research

Pharma



ORIG AMENDMENT

January 22, 2004

NIAF

Wm Peter Rickman
Director
Division of Labeling and Program Support
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

FPL

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VIA FEDERAL EXPRESS

ANDA 76-422

**Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)
LABELING AMENDMENT**

Dear Mr. Rickman:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w) submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with the provisions under 21 CFR §314.94 on August 5, 2002.

Reference is also made to the Agency correspondence dated December 31, 2003 stating labeling deficiencies. Altana has prepared this response in **comment**/response format.

Labeling Deficiencies

- 1. CONTAINER – The established name of this product is Ciclopirox Topical Suspension. Revise your container label accordingly. If you prefer, you may include the dosage form “lotion” underneath the established name as follows:**

**Ciclopirox Topical Suspension, USP
LOTION 0.77% (w/w)**

The product name on the container label has been revised to read:

**CICLOPIROX TOPICAL SUSPENSION, USP
0.77 (w/w) (LOTION)**

RECEIVED

JAN 23 2004

OGD/...

ANDA 76-422

Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)
LABELING AMENDMENT

2. CARTON – See “CONTAINER” comment.

The product name on the carton labeling has been revised to read:

**CICLOPIROX TOPICAL SUSPENSION, USP
0.77 (w/w) (LOTION)**

3. INSERT:

a. TITLE – See “CONTAINER” comment.

The product name in the title has been revised to read:

**CICLOPIROX TOPICAL SUSPENSION, USP
0.77 (w/w) (LOTION)**

b. TEXT – Revise your established name throughout your text to read “Ciclopirox Topical Suspension USP (Lotion) or “Ciclopirox Topical Suspension USP, 0.77% (Lotion)”.

The product name in the text of the insert labeling has been revised to read
Ciclopirox Topical Suspension USP, 0.77% (Lotion).

Please revise your labels and labeling, as instructed above, and submit 12 final printed copies for approval.

The container, carton and insert labeling have been revised as instructed and 12 final copies have been submitted in **Attachment I**.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. In order to keep your ANDA current, we suggest that you subscribe to the daily or weekly updates of new documents posted on the CDER web site at the following address-

<http://www.fda.gov/cder/cdernew/listserv.htm>

Altana acknowledges that prior to approval, it may be necessary to further revise the labeling subsequent to approved changes for the reference listed drug. In order to keep our ANDA current, we have subscribed to the daily updates of new documents posted on the CDER web site at the following address-

<http://www.fda.gov/cder/cdernew/listserv.htm>

ANDA 76-422

Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)

LABELING AMENDMENT

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.

To facilitate review of the submission, and in accordance with 21 CFR 314.94(a)(8)(iv) **Attachment II** contains a side by side comparison of the proposed labeling with our last submission with all differences annotated and explained.

If you have any questions or require additional information, please contact Ms. Audrey Zaweski, *Associate Director, Regulatory Affairs* at (631) 454-7677 extension 3007. Fax communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.



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

RJA/jb

Pharma



January 22, 2004

ORIG AMENDMENT

N/A/M

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
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www.altanainc.com

VIA FEDERAL EXPRESS

ANDA 76-422

Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)

MINOR AMENDMENT

Dear Mr. Rickman:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w) submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with the provisions under 21 CFR §314.94 on August 5, 2002.

Reference is also made to the Agency correspondence dated January 20, 2004 stating the following.

A. Deficiency

Labeling deficiencies were communicated to you via facsimile on December 31, 2003. You should address the issues in the December 31 communication prior to or concurrent with your response to this communication.

Altana Inc. has responded to the December 31, 2003 labeling deficiencies. **Attachment I** contains a copy of the Labeling Amendment cover letter dated January 22, 2004.

If you have any questions or require additional information, please contact Ms. Audrey Zaweski *Associate Director*, Regulatory Affairs at (631) 454-7677 extension 3007. Fax communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.

Robert J. Anderson, Esq.
Senior Director, Scientific Affairs
RJA/jb

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JAN 23 2004
OGD/CDL

5-1

Pharma



February 2, 2004

Carol Y. Kim, Pharm.D.
Clinical Reviewer
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

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ORIG AMENDMENT
N/AB

VIA FEDERAL EXPRESS

**ANDA 76-422
Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)
BIOEQUIVALENCE AMENDMENT – Request for Information**

Dear Dr. Kim:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w) submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with the provisions under 21 CFR §314.94 on May 28, 2002.

Reference is also made to the Agency correspondence dated January 23, 2004 requesting the following information.

In order to complete the review of a bioequivalence study with clinical endpoints for ANDA 76-422 (#ALT 00-0314-05), please submit the following information.

- 1. **Please provide a copy of Case Report Form (CRF) for the following patients:
T: 09 (122), 09 (310)
Reference: 13 (208), 09 (304), 06 (005), 06 (009), 09 (133)
Vehicle: 10 (48), 08 (474)**

Altana Inc. has provided a copy of the Case Report Form (CRF) for the following patients as requested. These copies are included in **Attachment I**.

T: 09^v(122), 09 (310)
Reference: 13 (208), 09 (304), 06 (005), 06 (009), 09 (133)
Vehicle: 10 (48), 08 (474)

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FEB 03 2004
OGD/CCLR

2. Please provide patient disposition by investigation site. You have provided “subject disposition by investigation site (Table 1.2)” in the original study report prepared by _____ (May 14, 2002). However, in the re-organized study report (April 18, 2003) prepared by _____ the tabulation of patient distribution by investigation site is not available. If the information originally provided by _____ is correct, then please state that in your response. If not, please provide patient disposition by investigation site per treatment group.

Altana Inc. is providing patient disposition by investigator site per treatment group. A CD is included in **Attachment II** containing the overall disposition tables and tables by site, along with the datasets.

If you have any questions or require additional information, please contact Ms. Audrey Zaweski *Associate Director, Regulatory Affairs* at (631) 454-7677 extension 3007. Fax communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.

Handwritten signature of Audrey Zaweski in cursive, with a small 'for' written above the end of the signature.

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

RJA/jb

Pharma



August 4, 2004

Frank Holcombe, Jr., Ph.D.
Associate Director
Division of Chemistry (HFD-600)
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

NIAW
6 AMENDMENT

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**VIA FACSIMILE and
FEDERAL EXPRESS**

ANDA 76-422

**Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w)
TELEPHONE AMENDMENT**

Dear Dr. Holcombe:

Reference is made to the Altana Inc. Abbreviated New Drug Application for Ciclopirox Topical Suspension USP (Lotion) 0.77% (w/w) submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act and in accordance with the provisions under 21 CFR §314.94 on May 28 2002.

Reference is also made to the August 4, 2004 teleconference held between FDA and Altana representatives to discuss the proposed expiration date of the product. Based on the review of the stability data submitted in the application, the FDA has requested that Altana choose one of the following options:

- assign a ~~—~~ month expiration date to the product or;
- add a 21-month test station to the Post Approval Stability Protocol and maintain the 24-month expiration period.

Altana Inc. has reviewed the FDA request and has revised the Post Approval Stability Commitment and Protocol to include a 21-month test station. Copies of the revised commitment and protocol are included with this submission.

If you have any questions or require additional information, please contact Ms. Audrey Zaweski *Associate Director*, Regulatory Affairs at (631) 454-7677 extension 3007. Fax communications can be made to (631) 756-5114.

Sincerely,
ALTANA INC.

Audrey Zaweski ^{for}

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

RECEIVED
AUG 05 2004
OGD / CDER