CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-374

CORRESPONDENCE

ALTANA

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

Federal Express

October 29, 1998

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 286
7500 Standish Place
Rockville, MD 20855-2773

NEW CORRES
NC
Noted
11/3/98

Re: ANDA 75-374
Diflorasone Diacetate Ointment, 0.05%

Dear Dr. Patel:

Reference is made to your communication of October 9, 1998 in which several deficiencies were noted in our application.

Reference is also made to our October 23, 1998 response. We request that Attachment 1 of our October 23, 1998 response be removed and replaced with the enclosed revised specification. It was noted after the amendment was submitted that the actual specifications for Specific Gravity were somehow omitted from the specification sheet. No other changes have been made to the In Process Specification submitted October 23, 1998.

Thank you for your cooperation in this matter.

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

VC:pj
Encl.

11-2 98

ALTANA

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

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October 23, 1998

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 286
7500 Standish Place
Rockville, MD 20855-2773

NDA ONLY AMENDMENT
N/AC

Re: ANDA 75-374 **MAJOR AMENDMENT**
Diflorasone Diacetate Ointment USP, 0.05%

Dear Dr. Patel:

Reference is made to our original Abbreviated New Drug Application submitted May 1, 1998 pursuant to Section 505(j) of the FDC Act.

Reference is also made to the Agency's letter of October 9, 1998 in which several deficiencies were noted in our application.

We wish to respond to the Agency's concerns as follows:

A. Deficiencies

Comment

1. Based on your data, please revise your in-process and finished product acceptance limits for degradation products.

Response

OCT 2 9 1998

GENERIC DRUGS

Page(s) _____

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

10/23/98

Response

Comment

10. Please provide all available room temperature stability data since trends were apparent in the provided data.

Response

Attachment 7 contains 18 month room temperature stability data.

In addition to the responses to the noted deficiencies, we also acknowledge:

1.) The firms referenced in our application should be in compliance with CGMP's at the time of approval; and

2.) Our bio study is under review and further comments may result.

Labeling Deficiencies:

Comment

1. Container (15 g, 30 g, 60 g)
   Satisfactory in draft.

Response

Attachment 8 contains final printed container labeling.

Comment

2. Container (15 g, 30 g, 60 g)
   Satisfactory in draft.

Response

Attachment 9 contains final printed carton labeling.

Comment

Insert

3. A. Description

Revise the third paragraph to read – Each gram of diflorasone diacetate ointment, for topical administration, contains....

B. Precautions

i. Information for patients

Revise the first bullet to read – This medication.....

ii. Pregnancy

Revise to delete the ultimate sentence, "Drugs of this class...."

C. Dosage and Administration

Revise the first sentence of the first paragraph to read – Diflorasone diacetate ointment should....

D. How Supplied

Revise to include – "Keep tightly closed."

Response

Attachment 10 contains final printed insert labeling.

As further requested, side-by-side comparison of the proposed final printed labeling and our originally submitted labeling may be found as follows:

Attachment 11 – Container labeling
Attachment 12 – Carton labeling
Attachment 13 – Insert labeling

We do acknowledge that the Agency reserves the right to request additional changes in our labels and/or labeling based upon changes in the innovator labeling, or further review of the application prior to approval.

We trust that with this additional information the Agency will deem our application approvable.

If there are any additional questions, please contact me at 516-454-7677, ext. 2091.

Sincerely,
Altana Inc.

Virginia Carman
Associate Director
Regulatory Affairs

VC:pj
Encl.

ALTANA

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

May 15, 1998

Ms. Denise Huie
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 TELEFAX (301) 594-1174
AND FEDERAL EXPRESS

Diflorasone Diacetate Ointment USP, 0.05%
ANDA 75-374
Facsimile Amendment

Dear Ms. Huie:

Reference is made to the abbreviated new drug application for Diflorasone Diacetate Ointment USP, 0.05%, ANDA 75-374 submitted on May 1, 1998 pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

Altana Inc. is submitting this Amendment in response to the FDA telephone request on May 14, 1998. The information is presented in **comment**/response format.

Reconciliation for the Executed Batch Record: How much bulk product was manufactured and how was it distributed between the 15, 30 and 60 gram tubes?

The reconciliation for the Diflorasone Diacetate Ointment USP, 0.05% exhibit batch Lot #9368 can be found on page 1745 of the original ANDA submission. For ease of review a copy of this page and a summary of the reconciliation have been included in this amendment.

If you require any additional information please contact me at (516) 454-7677 extension 2092.

Sincerely,

Altana Inc.

Cynthia I. Renger
Associate Director, Regulatory Affairs

CIR/ab

A:\ANDA75-374amend.wpd

APPROVAL PACKAGE SUMMARY FOR 75-374

ANDA: 75-374

FIRM: Altana Inc.

DRUG: Diflorasone Diacetate

DOSAGE: Ointment

STRENGTH: 0.05%

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 6/15/98.

BIO STUDY/BIOEQUIVALENCE STATUS: Bio satisfactory 10/1/98

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has provided satisfactory 3 months accelerated stability data at 40°C/75%RH and 18 months room temperature stability data at 25°C/60%RH for 15g, 30g and 60g tubes. Also submitted 8 weeks cycle study.

LABELING REVIEW STATUS: Labeling is satisfactory 3/31/99

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided a copy of the master formula and manufacturing procedure for maximum batch Also provided a copy of the executed batch lot #9368 for The firm will be using the same drug substance manufacturer , same equipment and same procedure.

COMMENTS: The application is approvable.

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 4/8/99

SUPERVISOR: Paul Schwartz, Ph.D. PS 4/9/99