CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-300

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NUMBER
1

2. ANDA NUMBER
76-300

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747
Telephone: 631-454-7677 ext. 2091 Fax: 631-756-5114

4. LEGAL BASIS for ANDA SUBMISSION
The basis of Altana's proposed ANDA for Fluticasone Propionate Ointment, 0.005% is the reference listed drug, Cutivate® Ointment, 0.005% (fluticasone propionate ointment) manufactured by Glaxo Wellcome Inc., NDA 19-957. The applicant certifies that there is one listed patent No 4335121 (expires November 14, 2003) covering the RLD (V.1.1, p. 9) and that Altana will not introduce this product to the market prior to the expiry of this patent. Altana further certifies that there is no unexpired exclusivity for the RLD.

5. SUPPLEMENT(s)
None

6. PROPRIETARY NAME OF DRUG
None

7. NONPROPRIETARY NAME
Fluticasone Propionate Ointment

8. SUPPLEMENT(s) PROVIDE(s) FOR
None

9. AMENDMENTS AND OTHER DATES

December 17, 2001	Original submission
February 13, 2002	New Correspondence

10. PHARMACOLOGICAL CATEGORY
For the relief of the inflammatory and pruritic manifestation of corticosteroid-responsive dermatosis.

11. HOW DISPENSED
Prescription

12. RELATED IND/NDA/DMF(s)

Product	Holder	DMF No.	LOA
[redacted]	[redacted]	[redacted]	V 1.1, p. 35 (attachment II)

See [redacted] section for other related DMF's.

13. DOSAGE FORM

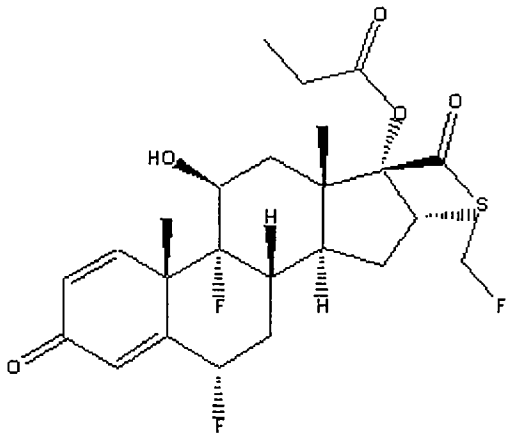
Ointment

14. POTENCY

0.005%

15. CHEMICAL NAME AND STRUCTURE

[(6α,11β,16α,17α)-6,9-difluoro-11-htdroxy-16-methyl-3-oxo-17-(1-oxopropoxy)androsta-1,4-diene-17-carbothecic acid, S-fluoromethyl ester; CAS No. 80474-14-2; $C_{25}H_{31}F_3O_5S$, MW. 500.5721



16. RECORDS AND REPORTS

None

17. COMMENTS

The following sections are not satisfactory: [redacted]

The bioequivalency and labeling reviews are pending. The overall establishment

inspection results are also pending. The product is non-USP and methods will be sent for method validation after methods related deficiencies have been resolved.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is not approvable (Minor Amendment).

19. REVIEWER AND DATE COMPLETED

Ramesh Sood/March 25, 2002, revised 4/8/02.

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CHEMISTRY REVIEW #1

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OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NUMBER
2

2. ANDA NUMBER
76-300

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747
Telephone: 631-454-7677 ext. 2091 Fax: 631-756-5114

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5. SUPPLEMENT(s)
None

6. PROPRIETARY NAME OF DRUG
None

7. NONPROPRIETARY NAME
Fluticasone Propionate Ointment

8. SUPPLEMENT(s) PROVIDE(s) FOR
None

9. AMENDMENTS AND OTHER DATES

December 17, 2001	Original submission
February 13, 2002	New Correspondence
4/22/02	New Correspondence (Bio)
7/29/02	Amendment (Labeling)
July 30, 2002	Minor Amendment
September 30, 2002	Telephone Amendment
October 18, 2002	Telephone Amendment
November 4, 2002	Telephone Amendment
November 5, 2002	Telephone Amendment

November 19, 2002 Telephone Amendment
November 20, 2002 Telephone Amendment

10. PHARMACOLOGICAL CATEGORY

For the relief of the inflammatory and pruritic manifestation of corticosteroid-responsive dermatosis.

11. HOW DISPENSED

Prescription

12. RELATED IND/NDA/DMF(s)

Product	Holder	DMF No.	LOA
[redacted]	[redacted]	[redacted]	V 1.1, p. 35 (attachment II)

13. DOSAGE FORM

Ointment

14. POTENCY

0.005%

15. CHEMICAL NAME AND STRUCTURE

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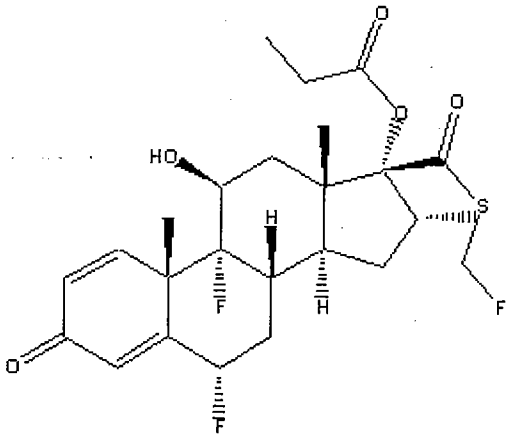

16. RECORDS AND REPORTS

None

17. COMMENTS

None

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable – Pending methods validation.

19. REVIEWER AND DATE COMPLETED

N. Nashed 1/8/03

Nashed E. Nashed, Ph.D. 12/10/02

Supervisor: James M. Fan 12/12/02 1/8/03

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CHEMISTRY REVIEW #2

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APPROVAL PACAGE SUMMARY FOR 76-300

ANDA: 76-300

FIRM: Altana Inc.

DRUG: Fluticasone Propionate

DOSAGE: Ointment

STRENGTH: 0.005%

CGMP STATEMENT/EIR UPDATE: EER is acceptable 9/12/02

BIO STUDY/BIOEQUIVALENCE: Bio is satisfactory 6/26/02

METHOD VALIDATION: Pending

STABILITY: [redacted]

LABELING REVIEW STATUS: Labeling is acceptable 9/9/02

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master batch record for intended production for [redacted] Also a copy of the executed batch record lot #G280 for [redacted] is included.
The firm will be using the same [redacted] manufacturer, same process, and same equipment.

COMMENTS: The application is approvable – pending method validation.

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 11/13/02

SUPERVISOR: James M. Fan 11/14/02

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NUMBER

3

2. ANDA NUMBER

76-300

3. NAME AND ADDRESS OF APPLICANT

Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747
Telephone: 631-454-7677 ext. 2091 Fax: 631-756-5114

4. LEGAL BASIS for ANDA SUBMISSION

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5. SUPPLEMENT(s)

None

6. PROPRIETARY NAME OF DRUG

None

7. NONPROPRIETARY NAME

Fluticasone Propionate Ointment

8. SUPPLEMENT(s) PROVIDE(s) FOR

None

9. AMENDMENTS AND OTHER DATES

December 17, 2001	Original submission
February 13, 2002	New Correspondence
4/22/02	New Correspondence (Bio)
7/29/02	Amendment (Labeling)
July 30, 2002	Minor Amendment
September 30, 2002	Telephone Amendment
October 18, 2002	Telephone Amendment
November 4, 2002	Telephone Amendment
November 5, 2002	Telephone Amendment

November 19, 2002	Telephone Amendment
November 20, 2002	Telephone Amendment
February 5, 2003	Telephone Amendment
March 15, 2004	Minor Amendment – Final Approval Requested
April 15, 2004	Telephone Amendment – Request for updated stability
April 16, 2004	Telephone Amendment – The firm commits to assign an 18 month expiration period to the 15 gram tube size.
May 12, 2004	Telephone Amendment – The firm commits to submit a Post Approval Supplement within 60 days of final approval with additional information and data regarding the viscosity testing procedure for the drug product.

10. PHARMACOLOGICAL CATEGORY

For the relief of the inflammatory and pruritic manifestation of corticosteroid-responsive dermatosis.

11. HOW DISPENSED

Prescription

12. RELATED IND/NDA/DMF(s)

Product	Holder	DMF No.	LOA
[redacted]	[redacted]	[redacted]	V 1.1, p. 35 (attachment II)

13. DOSAGE FORM

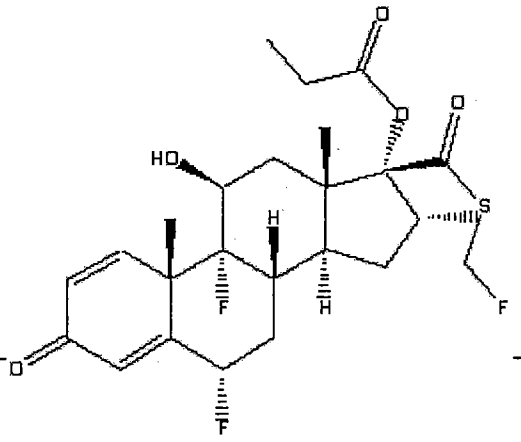
Ointment

14. POTENCY

0.005%

15. CHEMICAL NAME AND STRUCTURE

[(6α,11β,16α,17α)-6,9-difluoro-11-htdroxy-16-methyl-3-oxo-17-(1-oxopropoxy)androsta-1,4-diene-17-carbothecic acid, S-fluoromethyl ester; CAS No. 80474-14-2; **$C_{25}H_{31}F_3O_5S$**, MW. 500.5721



16. RECORDS AND REPORTS

None

17. COMMENTS

The firm has provided Minor Amendment – Final Approval Requested dated 3/15/04 included the following:

- [redacted]
- [redacted]
- The [redacted] limit was revised for the stability specifications.
- [redacted]
- [redacted] . The revised manufacturing instructions were provided.
- [redacted]

NOTE:

The firm has submitted Telephone Amendment dated May 12, 2004 to confirm the time line for the Post Approval Commitment discussed during the Teleconference dated May 11, 2004. The firm has indicated that they will submit a Post Approval Supplement within 60 days of final approval with additional information and data regarding the viscosity testing procedure for Fluticasone Propionate Ointment, 0.005%.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is Acceptable for Final Approval.

19. REVIEWER AND DATE COMPLETED

N. Nashed

Nashed E. Nashed, Ph.D. Date: 4/22/04
Revised: 4/30/04
Revised: 5/13/04 NN 5/13/04

Supervisor: James M. Fan 5/13/04

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CHEMISTRY REVIEW #3

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APPROVAL PACAGE SUMMARY FOR 76-300

ANDA: 76-300

FIRM: Altana Inc.

DRUG: Fluticasone Propionate

DOSAGE: Ointment

STRENGTH: 0.005%

CGMP STATEMENT/EIR UPDATE: EER is acceptable 9/12/02

BIO STUDY/BIOEQUIVALENCE: Bio is satisfactory 6/26/02

METHOD VALIDATION: Acceptable 4/10/03

STABILITY:

LABELING REVIEW STATUS: Labeling is acceptable 9/9/02

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master batch record for intended production for ——— Also a copy of the executed batch record lot #G280 for ——— is included.
The firm will be using the same ——————— manufacturer, same process, and same equipment.

COMMENTS: The application is approvable.

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 4/22/04

SUPERVISOR: James M. Fan 5/13/04