CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

64160

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. #1

2. AADA #64-160

3. NAME AND ADDRESS OF APPLICANT

E. Fougera & Co.
Division of Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

Telephone: 516-454-7677

4. LEGAL BASIS FOR SUBMISSION
21 CFR §453.522b

Reference drug: Cleocin T® (Clindamycin Phosphate) 1% Topical Gel manufactured by Upjohn. Signed certifications are provided (pp. 04-5) stating that there are no unexpired patents and that the drug is not subject to any exclusivity determination.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Clindamycin Phosphate Gel USP, 1% (base)

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

Firm:
Original Submission: 8/11/95
(Amendment 10/4/95)
Amendment 2/6/96 (Bio issue)

FDA:
Acknowledgment: 10/19/95
("Refuse to File" letter 9/26/95)
Bio N/A letter 12/6/95

10. PHARMACOLOGICAL CATEGORY
Antibacterial

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
AADA

13. DOSAGE FORM
Gel (Topical)

14. POTENCY
1% (as clindamycin)

15. CHEMICAL NAME AND STRUCTURE

$C_{18}H_{34}ClN_2O_8PS$ M.Wt.= 504.97

Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-*galacto*-octopyranoside 2-(dihydrogen phosphate)

16. RECORDS AND REPORTS
N/A

17. COMMENTS

This application is nicely prepared. Except concerns regarding specifications and stability studies, information and data submitted for chemistry issues are generally satisfactory.

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable (MAJOR)

19. REVIEWER: DATE COMPLETED:

Maria C. Shih 2/29/96

Redacted 11

pages of trade

secret and/or

confidential

commercial

information

Chem Review #1

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Application: **ANDA 64160/000**
Stamp: **14-AUG-1995** Regulatory Due:
Applicant: **FOUGERA**
60 BAYLIS RD
MELVILLE, NY 11747

Priority: Org Code: **600**
Action Goal: District Goal:
Brand Name:
Established Name: **CLINDAMYCIN PHOSPHATE**
Generic Name:
Dosage Form: **GEL (GEL)**
Strength: **1%**

FDA Contacts:			
M. ANDERSON	**(HFD-640)**	**301-827-5787**	**, Project Manager**
M. SHIH	**(HFD-643)**	**301-827-5849**	**, Review Chemist**
R. ADAMS	**(HFD-643)**	**301-827-5849**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 14-OCT-1999 by S. FERGUSON (HFD-324) 301-827-0062
WITHHOLD on 21-OCT-1996 by M. EGAS (HFD-322) 301-594-0095

Establishment: **2410271**
ALTANA INC
CANTIAGUE ROCK RD
HICKSVILLE, NY 11802

DMF No:
AADA No:

Profile: **OIN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **14-OCT-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **2432435**
ALTANA INC
60 BAYLIS RD
MELVILLE, NY 11747

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **05-OCT-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: **FINISHED DOSAGE OTHER TESTER**

Establishment:

DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **12-OCT-1999**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Decision: **ACCEPTABLE**

Reason: **DISTRICT RECOMMENDATION**

APPEARS THIS WAY
ON ORIGINAL

1. CHEMIST'S REVIEW NO. #2

2. AADA #64-160

3. NAME AND ADDRESS OF APPLICANT

E. Fougera & Co.
Division of Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

Telephone: 516-454-7677

4. LEGAL BASIS FOR SUBMISSION
21 CFR §453.522b

Reference drug: Cleocin T® (Clindamycin Phosphate) 1% Topical Gel manufactured by Upjohn. Signed certifications are provided (pp. 04-5) stating that there are no unexpired patents and that the drug is not subject to any exclusivity determination.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Clindamycin Phosphate Gel USP, 1% (base)

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

Firm:
Original Submission: 8/11/95
(Amendment 10/4/95)
Amendment 2/6/96 (Bio issue)

FDA:
Acknowledgment: 10/19/95
("Refuse to File" letter 9/26/95)
Bio N/A letter 12/6/95
Bio N/A letter 6/27/96

For this review:
Amendment 7/9/96 to N/A letter 3/19/96

10. PHARMACOLOGICAL CATEGORY
Antibacterial

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)
AADA

13. DOSAGE FORM
Gel (Topical)

14. POTENCY
1% (as clindamycin)

15. CHEMICAL NAME AND STRUCTURE

$C_{18}H_{34}ClN_2O_8PS$ M.Wt.= 504.97

Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-*galacto*-octopyranoside 2-(dihydrogen phosphate)

16. RECORDS AND REPORTS
N/A

17. COMMENTS

In Amendment 7/9/96 Firm responds to our concerns in order:

Q1a. Your specification for the active ingredient under "Related substances" is misleading due to the omission of solution (1) and solution (2) (Ref. BP 1993, Volume 1, page 165). Please revise.

A1a. The specifications for the active ingredient have been revised to clarify the Related Substances test specification (Attachment 1).

Comments:
Firm includes specifications for In the original submission only was identified as the bulk manufacturer. Ask Firm to clarify.

Q1b. Please identify some of the individual impurities.

A1b. Firm lists potential individual impurities and their relative retention times (RRT) with respect to clindamycin phosphate:

RRT	Compound

A chromatogram of clindamycin phosphate spiked with the impurities at levels about % is represented in Attachment 2.

Q1c. Is "Carbopol 974P" the synonym of "Carbomer 934P"? Are these two identical in formula and properties?

A1c. Firm states that Carbopol 974P is trade name for a type of carbomer 934P NF. also makes Carbopol 934P, which is also carbomer 934P NF. Although both Carbopols have the same chemical properties and conform to the NF monograph for carbomer 934P, is used in the synthesis of Carbopol 974P instead of the used in the synthesis of Carbopol 934P. As a result, Carbopol 974P has trace amounts of instead of the trace amounts of found in Carbopol 934P. Since is potentially more hazardous than and since the materials are otherwise identical, Firm selected Carbopol 974P as the type of carbomer 934 NF to use in their gel.

Q1d. Since "Allantoin" is not included in current USP, please explain the specification source you listed on page 116: "current USP". What is "CTFA"? What is the source of Reference Standard for "Identification"?

A1d. The source listed as "current USP" is in reference to the analytical methods described in the USP General Test chapter (<731> and <733>). "CTFA" is the abbreviation for the Cosmetic, Toiletry and Fragrance Assn., Inc.

The source for the Allantoin standard is (COA for product #A7878) with reference to the CTFA spectrum for identification purposes (Attachment 4).

Q2. In your "Composition Statement" for the finished product on page 61, please provide an extra column "kg/ kg" for each ingredient.

A2. The revised composition statement is included in Attachment 5; acceptable.

Q3. On Page 198, the information provided for the Altana Inc. facility located at 60 Baylis Road does not contain a description of the QC testing areas. Please clarify.

A3. The description of the QC testing areas is included in Attachment 6.

Q4. Please confirm that your intended maximum batch size is kg.

A4. Firm confirms that the intended maximum batch size is kg.

Q5. From the batch record for Exhibit lot #6453 on page 333, it is noted that the bulk yield is %, below the specified range %), due to some gel remaining in the equipment. What corrective action has been taken to prevent this from happening again?

A5. Firm states that the yield of % indicates that about kg of product remained in the kettle, transfer lines, transfer pump, and housing for the mesh strainer. Firm considers this is not an unusual amount (under the circumstances). Upon scale up, the kg will represent a smaller percentage of the batch. Gel remaining in the equipment has no adverse effect on the gel which is collected and used. The equipment is cleaned before being used to manufacture subsequent products.

Q6. Please specify the maximum holding period for the gel preparation before filling.

A6. Firm states that all non-emulsion (e.g., ointments, gels and otic solutions), non-sterile topicals and Swim Ear shall be compounded and filled within a six week interval from date of manufacture to initiation of continuous filling. (No interruptions exceeding five days.)

Q7. Please identify some of the degradation products and related substances listed under "Others". It is recommended that you complete this effort with some of the test chromatograms.

A7. (see also A1b)
The major degradation product of clindamycin phosphate is . The major degradation product of methylparaben is (Attachment 7).

RRT	Compound

Q8a. Please explain why the specification for "Viscosity" is different for release and for stability.

A8a. The release specifications are tighter than the stability ones to help ensure that normal changes during the expiry period will not result in test failures. Firm tightened the specifications and the revised specifications are included (Attachments 8 and 9).

Q8b. Regarding Degradation Products and Related Substances, we find the results do not justify the proposed high limits (i.e., % for "Clindamycin" and % for "Total"). Please comment.

A8b. Firm agrees that the limits are too high base on the results. They have tightened the specification (% for "Clindamycin" and % for "Total" and the revised limits are included (Attachments 8, 9 and 10). The updated stability data are included in Attachment 11. Data (3 month accelerated, 18 month RT and cycling studies) meet specifications.

Comments:

Labeling is acceptable per A.Payne 7/24/96.

Bio not acceptable (N/A letter 6/27/96).

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable (MAJOR - New bio study required).

19. REVIEWER: DATE COMPLETED:

Maria C. Shih 8/7/96

Redacted 9

pages of trade

secret and/or

confidential

commercial

information

Chem Review #2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

Copy

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE *(Check One)* Original	DATE March 13, 1996	PHONE NO. 594-0360	EER ID#
REQUESTORS NAME: M.Shih/J.Wilson	DIVISION: Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: ANDA 64-160			
BRAND NAME: Cleocin-T Gel	ESTABLISHED NAME: Clindamycin Phopshate Topical Solution		
DOSAGE STRENGTH: 1 % Gel in 7.5 g and 30 g			STERILE ☐Yes ☒ No
PROFILE CLASS:: OIN	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: E.Fougera & Co.			
APPLICANT'S ADDRESS: 60 Baylis Road Melville, NY 11747			
COMMENTS :			

FACILITIES TO BE EVALUATED
(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY	
Altana Inc. 30 Baylis Melville, NY 11747	testing	NEC			
2. Altana Inc. 55 Cantiague Rock Road Hicksville, NY 11802	manufactuer of the finished dosage form	OIN			
3.	maufacturer of NDS	CSN			
4.					
5.					

FOR HFD-324 USE ONLY:	DSQ	DATE RECEIVED
	CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: ANDA 64-159 HFD-643/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-643/JSimmons HFD-643/GJSmith
x:\wpfile\eerforms\64160

1. CHEMIST'S REVIEW NO. #3

2. ANDA #64-160

3. NAME AND ADDRESS OF APPLICANT
Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

Telephone: 516-454-7677
FAX: 516-756-5114

4. LEGAL BASIS FOR SUBMISSION
Reference drug: Cleocin T® Topical Gel (NDA #50-615, approved January 1987) manufactured by Pharmacia & Upjohn. Signed certifications are provided (pp. 04-5) stating that there are no unexpired patents and that the drug is not subject to any exclusivity determination.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Clindamycin Phosphate Gel USP, 1% (base)

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Original Submission 8/11/95
"Refuse to File" letter 9/26/95
Amendment 10/4/95
Acknowledgment: 10/19/95
Amendment 2/6/96 (Bio issue)
Bio N/A letter 12/6/95
Bio N/A letter 6/27/96
Amendment 7/9/96 to N/A letter 3/19/96
Amendment 4/26/99 to N/A letter (MAJOR) 8/19/96, Bio 6/12/98

10. PHARMACOLOGICAL CATEGORY
Antibacterial

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Gel (Topical)

14. POTENCY
1% (as clindamycin)

15. CHEMICAL NAME AND STRUCTURE
$C_{18}H_{34}ClN_2O_8PS$ M.Wt.= 504.97

Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-□-D-*galacto*-octopyranoside 2-(dihydrogen phosphate)

16. RECORDS AND REPORTS N/A

17. COMMENTS
There is no approved generic product for Clindamycin Phosphate Topical Gel 1%. Currently there is another application from Clay-Park Labs, Inc. (ANDA

Since the last review was done more than three years ago, some sections of the application are re-reviewed in this review.

In MAJOR Amendment 4/26/99 Firm responds to N/A letter 8/19/96 in order:

Q1. We note that you have included revised specifications for both . In the original submission only was identified as the bulk manufacturer. Please clarify.

A1. Altana states that is the only manufacturer of the active drug substance for which approval is sought. They have removed the reference to in the submitted documents.

Comment: From Stiefel's ANDA 64-136/S-002 (Clindamycin Phosphate Pledgets), we note that will terminate the production of clindamycin phosphate drug substance. Altana is expected to establish a new supplier after approval.

Q2. Please explain in detail the assay procedures for Clindamycin Phosphate potency and for the degradant content of the final product as reported in the stability studies.

A2. A copy of the detailed analytical procedures is included in Attachment 2.

Ask Firm how gel samples are taken from the tubes for release and stability assay analysis. It is noted from the stability report in Attachment 3 (page 14) that assay values for potency and degradants are provided in single values. Are they the average from different parts like those for "Homogeneity" (vertically positioned tubes are sliced open and samples are removed from top, middle and bottom; the bottom of the tube is near the cap, and top is near the crimp)?

Q3. It is noted that the updated stability data contain results from only the 30 g tube. Please also submit updated stability data for the 7.5 g tube.

A3. One year stability data for the 7.5 g tube is included in Attachment 3 (acceptable). Firm is not pursuing approval of the 7.5 g tube.

Q4. We await your submission of an in vivo bioequivalence study in response to the letter from our Division of Bioequivalence dated June 27, 1996.

A4. A copy of the final study report for an in-vivo bioequivalence study in included.

(Under review by BIO)

In this Amendment Firm also: (see review in appropriate sections)

1) answers the Chemistry Review 6/12/98 to BIO
Most information can be found in the original ANDA.
Some updates:

The specifications for Release, Stability and In-process (Attachments 5, 6, and 7) are revised (limits for and viscosity).

2) amends the application to include a 60 g tube presentation. Performance data are included in Attachments 16-19.

3) includes performance data for bio Lot A313 (Attachments 8-15).

Status Summary:

Labeling: Pending
EER: Pending
Sample: Not requested (USP drug)
Bio: Pending

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable (FAX AMENDMENT)

19. REVIEWER: DATE COMPLETED:

Maria C. Shih 9/29/99

Redacted 9

pages of trade

secret and/or

confidential

commercial

information

Chem. Review #3

FILL IN HHDH 64-160

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

VS

REQUEST TYPE *(Check One)* Original	DATE March 13, 1996	PHONE NO. 594-0360	EER ID # 4712
REQUESTORS NAME: M.Shih/J.Wilson	DIVISION: Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: ANDA 64-160			
BRAND NAME: Cleocin-T Gel	ESTABLISHED NAME: Clindamycin Phopshate Topical Solution		
DOSAGE STRENGTH: 1 % Gel in 7.5 g and 30 g			STERILE ☐Yes ☒ No
PROFILE CLASS:: OIN	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: E.Fougera & Co.			
APPLICANT'S ADDRESS: 60 Baylis Road Melville, NY 11747			
COMMENTS :			

FACILITIES TO BE EVALUATED
(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY	
1. Altana Inc. 60 Baylis Melville, NY 11747	testing	NEC	ALT 10 20193	AC AB	8/23/96
2. Altana Inc. 55 Cantiague Rock Road Hicksville, NY 11802	manufactuer of the finished dosage form	OIN	ALT 05 20194	AC	8/23/96
3.	maufacturer of NDS	CSN	ALT 2M 20236	UN	4/18/96
4.					
5.					

FOR HFD-324 USE ONLY	CSO	DATE RECEIVED 3/14/96
	CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: ANDA 64-159 HFD-643/Div File, HFD-617/JWilson, HFD-617/TAmes, HFD-643/JSimmons HFD-643/GJSmith
x:\wpfile\eerforms\64160

#1,2 acceptable
#3 UNACCEPTABLE

10/21/96

1. CHEMIST'S REVIEW NO. #4

2. ANDA #64-160

3. NAME AND ADDRESS OF APPLICANT
Altana Inc.
Attention: Virginia Carman
60 Baylis Road
Melville, NY 11747

Telephone: 516-454-7677
FAX: 516-756-5114

4. LEGAL BASIS FOR SUBMISSION
Reference drug: Cleocin T® Topical Gel (NDA #50-615, approved January 1987) manufactured by Pharmacia & Upjohn. Signed certifications are provided (pp. 04-5) stating that there are no unexpired patents and that the drug is not subject to any exclusivity determination.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME
Clindamycin Phosphate Gel USP, 1% (base)

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission 8/11/95
"Refuse to File" letter 9/26/95
Amendment 10/4/95
Acknowledgment: 10/19/95
Amendment 2/6/96 (Bio issue)
Bio N/A letters 12/6/95 and 6/27/96
Amendment 7/9/96 to N/A letter 3/19/96
Amendment 4/26/99 to N/A (MAJOR) 8/19/96, Bio 6/12/98
Amendment 10/26/99 to N/A (FAX) 10/22/99
Telephone Amendments 11/9/99 and 11/11/99

10. PHARMACOLOGICAL CATEGORY
Antibacterial

11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Gel (Topical)

14. POTENCY
1% (as clindamycin)

15. CHEMICAL NAME AND STRUCTURE
$C_{18}H_{34}ClN_2O_8PS$ M.Wt.= 504.97

Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-□-D-*galacto*-octopyranoside 2-(dihydrogen phosphate)

16. RECORDS AND REPORTS N/A

17. COMMENTS
There is no approved generic product for Clindamycin Phosphate Topical Gel 1%. Currently there is another application from Clay-Park Labs, Inc. (ANDA

In FAX Amendment 10/22/99 Firm answers in order:

Q1. For assay analysis, please explain how gel samples are taken from the tubes for release and stability purposes.

A1. Firm states that samples are extruded directly from the tube for finished product testing. For stability testing the tube is slit and the product is mixed before the analytical sample is taken.

Comments:
Since the tubes are stored sideways (see below), there is no need to remove samples from top, middle and bottom of the tubes as it is done for in-process samples.

Q2. It is not clear regarding the storage position for the stability samples. Are samples stored upright or sideways? Please clarify.

A2. Firm states that all tubes were stored sideways for all stability studies. Are they going to do that for future stability studies? Need confirmation.

Notes: Telephone conversation was initiated (see Memo dated 11/4/99 and 11/10/99) and in Amendments 11/11/99 Firm confirms that the stability samples **"will be stored on their sides at 25°C ± 2°C /60% ± 5% RH".**

Q3. It is noted that there are significant potency losses for the finished drug product during storage. Please submit additional long-term stability data to support the proposed expiry dating.

A3. Long term (24-month) stability data for 30 g and 60 g tubes are included. **Firm now proposes an 18-month expiration dating based on the data.**

Comments:
All data meet specifications except reading %) of one degradants (RRT 2.4) exceeds limit (NMT %). Significant potency loss and increased degradant levels are observed. The highest/lowest readings at 24-month stations are % for clindamycin phosphate (%), % for degradant clindamycin (NMT %), and % for total degradant (NMT %).

Q4. Results for seal integrity or leak testing of tubes/caps should be provided.

A4. Firm states that leak testing results are included in the stability testing reports under the heading "weight loss".

Comments:
Per our request, Firm comments in 11/9/99 Amendment that there is a slight evaporation of water. Firm proposes to tighten the weight loss to "**NMT** %" in the revised stability specification.

Status Summary:

Labeling:	Satisfactory 10/14/99
EER:	Acceptable 10/14/99
Sample:	Not requested (USP drug)
Bio:	Acceptable per M. Fanning 1/4/00

18. CONCLUSIONS AND RECOMMENDATIONS
Approval recommended (Chemistry satisfactory)

19. REVIEWER: Maria C. Shih
DATE COMPLETED: 11/30/99 (1/10/00)

Redacted 9

pages of trade

secret and/or

confidential

commercial

information

Chem-Review #4

OCT 22 1999

38. Chemistry Comments to be provided to the Applicant

ANDA: 64-160 **APPLICANT:** Altana Inc:

DRUG PRODUCT: Clindamycin Phosphate Topical Gel USP, 1% (base)

The deficiencies presented below represent FAX Deficiencies

1. For assay analysis, please explain how gel samples are taken from the tubes for release and stability purposes.

2. It is not clear regarding the storage position for the stability samples. Are samples stored upright or sideways? Please clarify.

3. It is noted that there are significant potency losses for the finished drug product during storage. Please submit additional long-term stability data to support the proposed expiry dating.

4. Results for seal integrity or leak testing of tubes/caps should be provided.

Sincerely yours,

/S/

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