CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65-027

CORRESPONDENCE

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

May 11, 2001

ORIG AMENDMENT
N/AM

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD # 630
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ATTENTION: Gary Buehler
Acting Director

Minor Amendment
Response to Microbiology Deficiencies

Re: ANDA 65-027 Clindamycin Phosphate Injection in 5% Dextrose
6mg (base)/mL, 12mg (base)/mL and 18mg (base)/mL

Abbott Laboratories herein responds to a July 25, 2000 facsimile request for additional microbiology information pertaining to the above named ANDA. The original ANDA application was submitted on August 31, 1998. Please find our response in **request**/response format.

Request 1:

Response:

FS

is

ish

MAY 14 2001
OGD
EVALUATION AND RESEARCH

Page(s) 3

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5/11/01

surfaces of the container (See Exhibit VI). At approximately day 7 of the 14 day incubation period, the bags
This allows the medium to again contact all the interior surfaces

We trust this information is complete. Please contact me if I may be of further assistance.

Sincerely,

Abbott Laboratories

Thomas P. Sampogna
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 935-3715
Fax: (847) 938-7867
e-mail: sampotp@hpd.abbott.com

5-01fda

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

May 24, 2000

Food and Drug Administration
Detroit District Office
Central Region
1560 East Jefferson Avenue
detroit, MI 48207-3179

ATTENTION: Shirley A.L Li
ANDA Team Leader

RE: ANDA 65-027 Clindamycin Injection in 5% Dextrose
6 mg/mL, 12 mg/mL and 18 mg/mL

SAMPLE REQUEST FOR METHOD VALIDATION TESTING

Abbott Laboratories hereby provides the analytical samples and test methods for the above-referenced abbreviated new drug application for the subject drug product packaged in a 50 mL plastic container.

This is in response to the Agency's letter from the Detroit District Office dated May 11, 2000 (received May 17, 2000) requesting the following items:

1. Clindamycin Phosphate USP Reference Standard Lot H-2, 3 vials

2. Clindamycin Phosphate Injection in 5% Dextrose 6 mg/mL, 6-50 mL units

3. Placebo Mixture for Degradant/Impurity testing, a suitable amount for analysis

4. Related Substances:
Clindamycin

Please send a suitable quantity of any, or all, related substance/degradant/impurity standards for peak identification, if available.

5. The latest copies of test methods, including assay for active ingredient, impurities, degradants, and related substances, analysis of purity, identification and specifications. If the methods already submitted are the latest, please state such in communication and there is no need to resend them.

6. A copy of the appropriate sheets from the analysts workbook for the analysis of the same lot with calculations, results and associated spectra and chromatograms.

7. Please include a copy of the Material Safety Data Sheet (MSDS) or any other special handling requirements.

We provide three vials of Clindamycin Phosphate USP reference standard and two of the major related substances: Clindamycin and Lincomycin. All other requested related substances are not identified and are summed together with Lincomycin related substance as percent total other impurities. Six units of Clindamycin Injection in 5% Dextrose, 6 mg base/mL, are included. Please note that this lot was tested after 24 month at 25°C storage in December 1999. A copy of the analysis is enclosed in Exhibit I. The latest copies of test methods are already submitted in the ANDA dated August 31, 1998.

The Placebo Mixture for Degradant/Impurity Test is not provided herein. Only EDTA in the placebo mixture is observed in the , chromatogram as shown in Exhibit II. The Material Safety Data Sheets for Clindamycin HCl, Lincomycin HCl and Clindamycin Phosphate are provided in Exhibit III.

If there are any further questions or if I can provide any more information, please feel free to contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JUL 25 2007

38. Chemistry Comments to be Provided to the Applicant

ANDA: 65-027 Applicant: Abbott Laboratories

Strengths: Clindamycin Phosphate Injection 6 mg (base)/mL
Clindamycin Phosphate Injection 12 mg (base)/mL
Clindamycin Phosphate Injection 18 mg (base)/mL

The deficiencies presented below represent FAX deficiencies.

Deficiencies:

Please refer to the attached MICROBIOLOGY deficiencies.

Sincerely yours,

Vilayat Sayed

for

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

Microbiology Comments to be Provided to the Applicant

ANDA: 65-027 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Clindamycin Phosphate Injection in 5% Dextrose

A. Microbiology Deficiencies:

1.

2.

3.

4.

Page(s) 1

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

discuss.

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. The above deficiencies represent a minor amendment.

Sincerely yours,

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

June 16, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD # 630
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ORIG AMENDMENT
N/AM

ATTENTION: Gary J. Buehler
Acting Director

Re: ANDA 65-027 Clindamycin Injection in 5% Dextrose
6 mg/mL, 12 mg/mL and 18 mg/mL

MAJOR AMENDMENT – Microbiological Response

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product. We are responding to the Agency's faxed letter dated April 27, 2000 regarding the microbiology review.

Please note that the numbering systems for the ANDA volumes between Abbott Laboratories and the Agency were different. Volume 1.6 as referred by the Agency is Abbott's volume 6 of 10 in the original ANDA. We will use the Agency's numbering system, i.e., volume 1.6 or volume 1.7, in the following responses to the Agency's comments:

COMMENT: **"1. Regarding manufacturing facility and processes:**

a.

- **The type and location of the solution line from the filling tank to the**

RESPONSE:

JUN 19 2000
OGD
EVALUATION AND RESEARCH

Page(s) 10

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

6/16/00

COMMENT:

RESPONSE:

We trust that this submission is complete. If there are any further questions, please contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Noted: To See Zuk m Anderson 5/30/00

May 24, 2000

VIA OGD AMENDMENT FAX

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD # 630
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ATTENTION: Gary J. Buehler
Acting Director

Re: ANDA 65-027 Clindamycin Injection in 5% Dextrose
6 mg/mL, 12 mg/mL and 18 mg/mL

FAX AMENDMENT

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product. We are responding to the Agency's faxed letter dated May 8, 2000 regarding the chemistry review.

The Agency's comments are as follows:

COMMENT: **"The deficiencies presented below represent FAX Deficiencies:**
1. Please provide the number of samples tested in your bulk holding time study."

RESPONSE: There were two bulk holding time studies performed. Study , was performed for List # 9623, 18mg/mL, and was performed for List # 9621, 6mg/mL. The number of samples tested for each study protocol is as follows:

TEST	# Sample Tested @ 36 hrs	# Sample Tested @ 42 hrs	# Sample Tested @ 48 hrs
Bioassay (BET)	1	1	1
Solution Bioburden	1	1	1
Chemistry	1	1	1

COMMENT: **"2. It is not clear when the in-process recbulk sample is drawn during the manufacturing process."**

RESPONSE: The in-process recbulk (recirculating bulk) sample is drawn at the end of the mixing time.

Page(s) 1

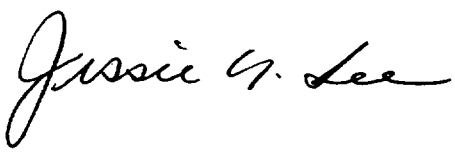
Contain Trade Secret, Commercial/Confidential Information and are not releasable.

5/24/00

We trust that this submission is complete. If I can provide any more information, please feel free to contact me.

Sincerely,

ABBOTT LABORATORIES



Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

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attachment

MAY 18 2000

38. Chemistry Comments to be Provided to the Applicant

ANDA: 65-027 Applicant: Abbott Laboratories

Strengths: Clindamycin Phosphate Injection 6 mg (base)/mL
Clindamycin Phosphate Injection 12 mg (base)/mL
Clindamycin Phosphate Injection 18 mg (base)/mL

The deficiencies presented below represent FAX deficiencies.

Deficiencies:

1. Please provide the number of samples tested in your bulk holding time study.

2. It is not clear when the in-process recbulk sample is drawn during the manufacturing process.

3. In your response to our April 22, 1999 deficiency letter you have indicated that the specification for Clindamycin related substances is now % and percentage Clindamycin is According to the protocol provided in Exhibit VI there is no separate specification for percent Clindamycin. The stability protocol includes specifications for Clindamycin related substances and total other related substances, both of which are determined by Abbott in-house test Please clarify your statement regarding stability specifications.

4. The release specifications for Clindamycin related substances, total other related substances and should be tightened as your stability specifications have been. Please revise the release specifications accordingly.

5. The revised stability protocol testing schedule part (A) states that the first three marketed lots of the product will be tested according to the protocol. Thereafter, at least one production lot will be tested annually. However, the stability protocol part (B) indicates that only the first three lots will be tested at 0, 3, 6, 9, 12, 18 and 24 months. All other lots will be tested at 0, 6, 12, 16, and annually through the expiration date. Reduction of stability testing cannot be done without submission of a prior

approval supplement. Please revise stability protocol part (B) to include all testing intervals for at least one lot annually after the first three commercial lots have been tested.

Sincerely yours,

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

Microbiology Comments To Be Provided To The Applicant

ANDA: 65-027 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Clindamycin Phosphate injection in 5% Dextrose

A. Microbiology Deficiencies:

1. Regarding manufacturing facility and processes:

a.

b.

c.

d.

2. Regarding environmental monitoring:

a. Please provide a site map of the room where the Isolator was located and identify sites from where environment samples were collected.

b. It is not clear how samples were collected from the inside of the microbiological testing. How was the quality of air in monitored as containers were formed and filled? Please describe.

c. You have provided Action Levels for environmental monitoring in (8/26/99) and These documents did not list Alert and Action Levels for the Isolator surfaces in contact with the product after sterilization, please comment.

d. Please describe the test procedures used to monitor

environmental test sites including types of growth media used, incubation time and temperature etc.

e. Records of environmental monitoring on pages 172-181 of volume 1.6 lists values under column 'Results' in fractions (0.1, 0.4 etc). Please explain how the fractions were calculated and provide the rationale for their use.

3. Regarding sterilization and depyrogenation:

a.

b. ion the

c.

d. ide

ies in

e. ct

f.

Page(s) 2

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microbiology volume 1.1 of the ANDA.

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. The above deficiencies represent a major amendment.

Sincerely yours,

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

ORIG AMENDMENT
NIFAF

May 16, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD # 630
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ATTENTION: Gary J. Buehler
Acting Director

Re: ANDA 65-027 Clindamycin Injection in 5% Dextrose
6 mg/mL, 12 mg/mL and 18 mg/mL

MINOR AMENDMENT WITH FPL

Abbott Laboratories hereby amends the above-referenced abbreviated new drug application for the subject drug product. We are responding to the Agency's faxed letter dated April 14, 2000 regarding the labeling review.

The Agency's comments are as follows:

COMMENT: **"Labeling Deficiencies:**

1. **CONTAINER: 300 mg/50 mL, 600 mg/50 mL and 900 mg/50 mL**
   Please increase the prominence of the route of administration on the principal display panel."

RESPONSE: The prominence of the route of administration, "For I.V. use only." was increased per Agency's comment. In addition, the recycle and latex free symbols were added with revision date. The side-by-side comparison of the proposed container labeling with the last submission is provided in Exhibit I. The final printed container labels are provided in Exhibit II.

COMMENT: **"2. CARTON: 300 mg/50 mL x 24, 600 mg/50 mL x 24 and 900 mg/50 mL x 24**

a. **We encourage that you revise the net quantity statements on the side panels to be the same as the principal display panel (i.e., "24 x Single-dose container" rather than "Single-dose container")**
b. **We note that the HOW SUPPLIED section of the insert labeling indicates that 25 containers, not 24 containers, would be packaged in a carton. Please revise the net quantity on your carton and/or comment."**

RESPONSE: The innovator, Upjohn, has recently changed the net quantity in the carton package from a 24 container package to a 12 container package. Hence, we are matching with the innovator's new packaging configuration.

The top panel of the innovator's carton label was designed with perforation line for top opening. The innovator's carton labels only appear on four side panels. The Abbott proposed carton labels are identical in content to the draft labeling submitted on October, 29, 1999 except for the number of containers per carton which was changed from "24 Single-dose containers" to "12 Single-dose containers". In addition, Abbott keeps the top panel label and four side panel labels. The bottom tray was eliminated. A side-by-side comparison of the innovator's and Abbott's proposed carton labels is provided in Exhibit III. The final printed carton labeling is attached in Exhibit IV.

COMMENT: **"3. INSERT**

a. BOXED WARNING - Second paragraph, last sentence:
... indicate that a toxin... [add "that"]

b. DESCRIPTION
i. Include the route of administration. We refer you to 21 CFR 201.57(a)(ii)
ii. We encourage the inclusion of pH range of your drug product.

c. CLINICAL PHARMACOLOGY- First and second paragraphs:
Replace the term "disappearance" with "elimination". [3 instances]

d. PRECAUTIONS- Usage in Newborns and Infants
... in pediatric patients from...

e. DOSAGE AND ADMINISTRATION - Include the following text as the first paragraph in a prominent manner.
Dosing references to the intramuscular route of administration are for informational purpose only.

f. DIRECTIONS FOR USE
i. This is a subsection under DOSAGE AND ADMINISTRATION section. Please reduce the prominence of this subsection heading to be consistent with other subsection headings.
ii. Preparation for administration - Item 3:
... directions of accompanying... - [add "of"]

g. HOW SUPPLIED
See comment (b) under CARTON."

RESPONSE: We have revised the insert labeling per Agency's comments. The quantity per carton has also been changed from 25 to 12 in the HOW SUPPLIED section. The side-by-side comparison of the proposed insert labeling with the last submission is provided in Exhibit V. The final printed labeling is attached in Exhibit VI.

We trust that this submission is complete. If I can provide any more information, please feel free to contact me.

Sincerely,

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
Fax: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

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attachment

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

October 29, 1999

ORIG AMENDMENT
N|A C

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD # 630
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855

ATTENTION: Douglas Sporn
Director

Re: ANDA 65-027 Clindamycin Phosphate Injection in 5% Dextrose
6mg/mL, 12mg/mL and 18mg/mL

RESPONSE TO CHEMISTRY AND LABELING DEFICIENCIES
MAJOR AMENDMENT

Abbott Laboratories hereby amends the above referenced abbreviated new drug applications for the subject drug products submitted August 31, 1999. We are responding to the Agency's facsimile action letter dated April 22, 1999. Contained herein please find our response in **request**/response format.

A. Chemistry Deficiencies

REQUEST: **1.** We note that [illegible]

RESPONSE: [illegible] rm

REQUEST: **2.**

RESPONSE:

REQUEST: **3.**

Page(s) 2

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10/29/99

RESPONSE: Appended in Exhibit VII is updated room temperature stability data through 12 months.

B. Labeling Deficiencies

REQUEST: 1. General Comment

On November 15, 1998, the official USP monograph title for "Clindamycin Phosphate Injection" was replaced with "Clindamycin Injection". Please revise the established name on your container labels, carton labeling and insert labeling accordingly. We refer you to USP 23, supplement 9.

2. Container: 300mg/50mL, 600mg/50mL and 900mg/50mL

Make the following revisions:

a. Revise "single dose" to read "single dose container"
b. Due to the USP title revision, make the following Revisions:

i. Delete the text "equivalent to" and "clindamycin" Which appears immediately before and after the strength.

ii. Add an asterisk following the strength, "___mg*".

Clindamycin Injection
In 5% Dextrose
300 mg* per 50 mL

iii. * Each 50mL contains: Clindamycin Phosphate equivalent 300mg clindamycin and...

c. Add the following statement:
...insert. Sterile, nonpyrogenic. Do not add supplementary medication ...

d. Replace the statement, "use only if solution is clear and container is undamaged" with the statement, "check for minute leaks and solution clarity".

e. **Replace the statement, "Avoid excessive heat" with the statement, "Avoid temperatures above 30°C".**

3. CARTON: **300mg/50mL x 24, 600mg/50mL x 24 and 900mg/50mL x 24**

a. **See comments under CONTAINER.**

b. **Add the following statement:**

...heat. See package insert for complete product information.

3. INSERT

a. General Comment

Due to changes in the approved labeling of the reference listed drug, Cleocin Phosphate® Sterile Solution (Pharmacia & Upjohn Company, acknowledged and retained June 8, 1998 and revised December 1997) revise your package insert labeling to be in accord with the attached insert labeling. You may omit revisions that do not apply to your application (i.e. text pertaining to vials, Pharmacy Bulk Package and ADD-Vantage vials).

b. DESCRIPTION

Revise the first sentence to read, "Clindamycin Injection in..."

c. HOW SUPPLIED

i. **See comment under DESCRIPTION.**
ii. **Define "FFS".**

RESPONSE: Abbott Laboratories acknowledges all of the comments recommended by the Agency pertaining to this application. And has incorporated all changes into the following exhibits.

Exhibit VIII contains changes to the container.

Exhibit IX contains changes to the carton.

Exhibit X contains changes to the package insert.

Additionally, under **HOW SUPPLIED**, "FFS" is defined as form fill seal.

We trust this information is complete. Please contact me if I may be of further assistance.

Sincerely,

Abbott Laboratories,

Thomas P. Sampogna
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 935-3715
Fax: (847) 938-7867
10-99fda

APR 22 1999

1.1

38. Chemistry Comments to be Provided to the Applicant

ANDA: 65-027 Applicant: Abbott Laboratories

Strengths: Clindamycin Phosphate Injection 6 mg (base)/mL
Clindamycin Phosphate Injection 12 mg (base)/mL
Clindamycin Phosphate Injection 18 mg (base)/mL

The deficiencies presented below represent MAJOR deficiencies.

Deficiencies:

1. We note that Form FDA 356h submitted for your new correspondence dated October 13, 1998, is for a different dosage form. Please correct the form as required.

2. Comparative spectra for a traceable USP reference standard and a test sample are missing.

3. We acknowledge your proposed maximum holding time of hours for the bulk solution (page 6.50). Data from a holding time study, which includes chemical stability, bioburden and endotoxin testing, are not included. Please provide.

4. Please confirm when the samples are taken from the bulk solution (e.g., after . Also, the pH range stated on page However, your blank batch records specify the pH range as Please clarify this discrepancy. In addition, please provide a listing of the proposed controls for scale-up purposes to be observed during specific steps of your manufacturing process.

5. The solution bioburden test requirement specified on page 7.444 is found difficult to evaluate. Please confirm the alert and action limits.

6. Comparative degradation profile data vs. the RLD should be included.

7. The clindamycin & total other related substances & single largest other related compound and related substances proposed release and stability specifications are considered to be too broad. It is recommended that these be revised to be more consistent with the release and stability data obtained for the demonstration batches.

8. Please be aware that the reduction of stability testing intervals in your stability protocol requires the submission of a (post-approval) supplemental application following

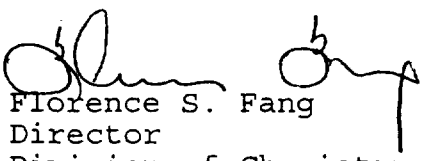
confirmation of tentative expiration dating based upon full term data on three production batches. Please acknowledge and revise/resubmit your stability protocols' proposed test intervals to be followed for the first three commercial production lots and the one lot yearly thereafter.

9. The stability protocol proposed tests and specifications found on page 10-380 shows the clindamycin related substances specification to be However, your stability report form shows the percentage of clindamycin as an impurity specification to be Also, we noticed that the percentage of lincomycins is not reported in your stability report form. Please explain the subject discrepancy and correct as appropriate.

10. Updated room temperature stability data for the demonstration batches should be provided.

11. Please note that controlled room temperature as specified in the USP is 20-25°C, excursions allowed between 15-30°C.

Sincerely yours,



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

BIOEQUIVALENCY COMMENTS

AADA: 65-027 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Clindamycin Phosphate in 5% Dextrose, 6, 12, and 18 mg/mL

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

BIOEQUIVALENCY COMMENTS

AADA: 65-027 APPLICANT: Abbott Laboratories

DRUG PRODUCT: Clindamycin Phosphate in 5% Dextrose, 6, 12, and 18 mg/mL

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 65-027

Abbott Laboratories
Attention: Thomas P. Sampogna
200 Abbott Park Rd., D-389, AP30
Abbott Park, IL 60064-3537

OCT 26 1998

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 made to the telephone conversation dated October 1, 1998 and your correspondence dated October 13, 1998.

NAME OF DRUG: Clindamycin Phosphate Injection in 5% Dextrose, 6 mg(base)/mL, 12 mg(base)/mL and 18 mg(base)/mL

DATE OF APPLICATION: August 31, 1998

DATE (RECEIVED) ACCEPTABLE FOR FILING: September 9, 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,

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

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

October 13, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

NEW CORRESP.
NC

ATTENTION: Douglas Sporn
Director

RE: ANDA 65-027 Clindamycin Phosphate Injection in 5% Dextrose
New Correspondence

On October 1, 1998, a teleconference was held between Lt. Greg Davis of the Agency and Mr. Thomas P. Sampogna of Abbott Laboratories. Lt. Davis acknowledged receipt of the above named ANDA and requested that additional information be forwarded regarding the application. Specifically: 1) Include any information that would confirm HPD bulk drug testing upon receipt from the vendor. 2) Correct the batch size for the Blank Batch Record (page 6-297 of the original application). 3) Confirm the lot of bulk drug identified in the chromatogram from the bulk drug vendor is the same as the lot used in the drug product and 4) Supply a Letter of Authorization to the Drug Master File for the Form Fill Seal container referenced throughout the application.

Attached in Exhibits I through IV is the following information:

Exhibit I	HPD C of A for incoming bulk drug.
Exhibit II	Corrected batch size for the Blank Batch Record
Exhibit III	Confirmation of bulk drug lot number from vendor
Exhibit IV	Letter of Authorization and confirmation from FDA that the DMF for Form Fill Seal container was accepted.

We trust this information is complete. Please contact me if I may be of further assistance.

Sincerely,

Abbott Laboratories

Thomas P. Sampogna

Thomas P. Sampogna
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 935-3715
Fax: (847) 938-7867
10-98fda

RECEIVED
OCT 15 1998
GENERIC DRUGS

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

505(j)(2)(a) OK
10/16/98
Gregory S. Davis

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GENERIC DRUGS

August 31, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS, HFD #630
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855

ATTENTION: Douglas Sporn
Director

RE: Clindamycin Phosphate Injection in 5% Dextrose

ORIGINAL ABBREVIATED NEW DRUG APPLICATION

Abbott Laboratories hereby submits an abbreviated new drug application for Clindamycin Phosphate Injection in 5% Dextrose, 300mg, 600mg and 900mg per 50mL plastic container in accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act. This container has been developed for use in the manufacture of products that are heat sensitive. Additionally, because of the barrier characteristics of the container, an overwrap is not required. The dosage form and manufacturing site may be described as follows:

List Number	Dosage Form	Manufacturing Facility
9621	Equivalent to 6mg Base/mL 50mL Plastic Container	Rocky Mount, NC
9622	Equivalent to 12mg Base/mL 50mL Plastic Container	Rocky Mount, NC
9623	Equivalent to 18mg Base/mL 50mL Plastic Container	Rocky Mount, NC

The basis for this submission is clindamycin phosphate injection, which is currently manufactured for Pharmacia and Upjohn Company (formerly known as the Upjohn Company) Kalamazoo, Michigan 49001 by Baxter Healthcare Corporation, Deerfield, Illinois, under the name Cleocin Phosphate® (clindamycin phosphate injection in 5% dextrose). The NDA for this product is 50-639. Cleocin Phosphate® is marketed as a 6mg base/mL, 12mg base/mL and an 18mg base/mL concentration in 5% Dextrose in 50mL Plastic Containers.

We submit this application in accordance with MAPP 6020.2, "Applications for Parenteral Products in Plastic Immediate Container", issued September 6, 1996. This application is submitted in accordance with MAPP 6020.2 in that 1) This product duplicates an approved product listed in the current edition of *Approved Drug Products with Therapuetic Equivalence Evaluations* (The Orange Book) namely Cleocin Phosphate® (clindamycin hydrochloride injection) in 5% Dextrose. 2) Studies in plastic containers were not required beyond confirmatory testing.

The Policy additionally states that " This policy applies to applications for parenteral products packaged in plastic immediate containers regardless of whether the plastic material has been previously used to package an approved drug". The plastic material chosen to package the finished product is a Form Fill Seal plastic container and is sterilized via an method utilizing a le. Details regarding the Form Fill Seal plastic container may be found in our DMF for the form fill seal container (**DMF number to be assigned. As soon as this information is received, it will be forwarded to the Office of Generic Drugs)** . The sterilization assurance information is found in Section XI, Manufacturing and Processing Instructions section of this submission.

Please refer to the accompanying Table of Contents for a list of the data supporting this submission. These data have been presented in volumes consistent with the Office of Generic Drugs Policy and Procedure Guide #30-91 dated 4/10/91, entitled ORGANIZATION OF AN ABBREVIATED NEW DRUG APPLICATION AND AN ABBREVIATED ANTIBIOTIC APPLICATION.

Abbott Laboratories will manufacture the finished dosage form at its currently approved Rocky Mount, North Carolina facility. Certain portions of Rocky Mount, North Carolina's Drug Master File have been reproduced here for ease of review. However, please refer to Drug Master File for a *full* description of this facility.

In compliance with 21 CFR 314 covering FDA pre-approval inspections of manufacturing sites, Abbott Laboratories has submitted a complete copy of the CMC section from this application ("designated as the field copy") to the Atlanta FDA district office with inspection responsibilities for the Abbott Laboratories manufacturing site listed in this application. Our certification statement regarding the field copy immediately follows this cover letter.

We also include in Section XXI of this application the "Certification Requirement of All applications For Approval of a Drug Product," as required by the Generic Drug Enforcement Act of 1992.

We request twenty-four (24) months expiration dating for this product based on the accelerated stability data enclosed. At the request of the Agency, we will provide samples of the drug substance and finished dosage forms.

We trust that this submission is complete.

Sincerely,

Thomas P. Sampogna
for

Thomas P. Sampogna
Manager, Regulatory Affairs
Hospital Products Division
Phone (847) 935-3715
Fax (847) 938-7867
Clindamycin/ffs