CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65-027

ADMINISTRATIVE DOCUMENTS

ANDA APPOVAL SUMMARY

ANDA: 65-027

DRUG PRODUCT:
Clindamycin Phosphate Injection in 5% Dextrose, 300 mg/50 mL
Clindamycin Phosphate Injection in 5% Dextrose, 600 mg/50 mL
Clindamycin Phosphate Injection in 5% Dextrose, 900 mg/50 mL

FIRM: Abbott Laboratories

DOSAGE FORM: Parenteral

STRENGTHS: 300 mg/50 mL, 600 mg/50 mL and 900 mg/50 mL

CGMP STATEMENT/EIR UPDATE STATUS: Signed cGMP certificates were provided on page 5-236 and 5-236A, Vol. 1.5. An update on EER was requested by the project manager 6/7/00.

BIO STUDY: A comparison of the applicant's product to Pharmacia and Upjohn's Cleocin® Phosphate (clindamycin phosphate injection in 5% dextrose) was found to be acceptable on 11/12/98. The Bioequivalence Division granted a waiver for the submission of *In Vivo* bio-study data.

METHOD VALIDATION -(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S): The drug product is a non-compendial product. The district laboratory has tested the methods provided in the ADNA and found them to be satisfactory.

STABILITY -(ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?): Accelerated and room temperature stability data support the proposed 24-month expiration date. Containers used in the stability study were identical to those described in the application for commercial production.

LABELING: Refer to the labeling "Approval Summary".

STERILIZATION VALIDATION (IF APPLICABLE): The Microbiology Division has reviewed the sterilization procedure and found the process to be acceptable. Refer to the Micro review dated 5/22/01.

SIZE OF BIO BATCH (FORM"S SOURCE OF NDS OK?): Exhibit batches 34-377-DK, 34-376-DK and 34-375-DK used for stability and bio-studies were manufactured with bulk drug substance supplied by . The

exhibit batches were manufactured to produce theoretical yields o
Liters (34-377-DK) Liters (34-376-DK), Liters (34-375-DK).

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?): See above

PROPSED PRODUCTION BATCH - (MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?): The proposed production batch size is liters for all dosage strengths. The manufacturing process described in the blank master record is the same as that described in the exhibit batch records.

CHEMIST: Susan Zuk **DATE:** 5/30/01
SUPERVISOR: Richard Adams **DATE:** 5/31/01

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 65-027

Date of Submission: August 31, 1998

Applicant's Name: Abbott Laboratories

Established Name: Clindamycin Injection in 5% Dextrose, 6 mg(base)/mL, 12 mg(base)/mL and 18 mg (base)/mL

Labeling Deficiencies:

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: 300 mg/50 mL, 600 mg/50 mL and 900 mg/50 mL

   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 50 mL contains: Clindamycin Phosphate equivalent 300 mg 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: 300 mg/50 mL x 24, 600 mg/50 mL x 24 and 900 mg/50 mL x 24

a. See comments under CONTAINER.

b. Add the following statement:

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

4. 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. <u>You may omit revisions that do not apply to your application (i.e., text pertaining to vials, Pharmacy Bulk Package and ADD-Vantage vials.</u>

b. DESCRIPTION

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

c. HOW SUPPLIED

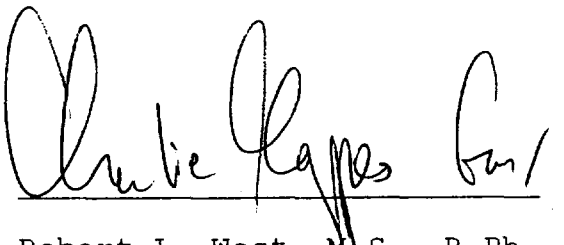
i. See comment under DESCRIPTION.

ii. Define "FFS".

Please revise your labels and labeling, as instructed above, and submit in draft.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

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.



Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment: Cleocin Phosphate® insert labeling