CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

65-049

CORRESPONDENCE

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 23, 2000

TO: ANDA 65-049, Clindamycin Phosphate Topical Solution 1%, Swabs; Clay-Park

FROM: Richard C. Adams

SUBJECT: Telephone Amendment: Physicochemical evaluation of pads

This drug product consists of a 1% solution of clindamycin phosphate in about water/isopropanol/propylene glycol, in which are submersed 60 pads constructed of [redacted], all contained in a polypropylene jar. Although the firm provided the appropriate references to the GRAS status of the container/closure system, no such information was provided for the rayon/nylon pads and such affirmation could not be obtained for all the materials used in the manufacture of the pads. Therefore we asked the firm to provide data on the physicochemical properties as per USP <661>, including data on the extractable.

A telephone amendment was received this date with the results. The firm performed the extractable using 100% water and 100% isopropanol. In both cases, the results were within the USP <661> limits.

Conclusions:

1. The rayon/polypropylene pads used in this drug product meet the criteria of the USP<661> physicochemical tests and are therefore acceptable.
2. The results of this testing provide a benchmark for [redacted] pads.

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

FIELD COPY CERTIFICATION

This is to certify that the field copy (third copy) of the ANDA for Clindamycin Phosphate Pledgets, 1% is a true copy of the original submission to the FDA. The field copy has been forwarded to the local New York District Office for their reference.

Candis Edwards
Director of Regulatory Affairs
Clay-Park Labs, Inc.

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

May 23, 2000

Mark Anderson
Food and Drug Administration
Office of Generic Drugs, CDER
Division of Labeling and Program Support
Document Control Room
Metro Park North 2, HFD-617
7500 Standish Place
Rockville, MD 20855

Re: Telephone Amendment to ANDA # 65-049, Clindamycin Phosphate Pledgets, 1%

Dear Mr. Anderson:

As per our telephone conversations on May 15 and May 23, 2000, Clay-Park Labs, Inc. hereby provides the USP<661> physicochemical – plastic test results performed on the pads (**Attachment 1**), as requested. The results of the test meet the requirements of USP<661> and demonstrate that the pads are safe for use in our Clindamycin Phosphate Pledgets, 1%, drug product.

We anticipate that the information provided in this correspondence will satisfy any outstanding CMC technical issues pending approval of Clay-Park Labs, Inc.'s ANDA for Clindamycin Phosphate Pledgets, 1%.

Should you have any comments or require any further clarification on this telephone amendment, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,

Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

CERTIFICATION

This is to certify that the field copy of the telephone amendment to ANDA # 65-049, dated May 23, 2000, for Clindamycin Phosphate Pledgets, 1% is a true copy of the original submission to the FDA. The field copy has been forwarded to the local New York District Office for their reference.

Candis Edwards
Director of Regulatory Affairs
Clay-Park Labs, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Clay-Park Labs, Inc.	May 23, 2000
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(718) 960-9976	(718) 960-0111

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE
Clay-Park Labs, Inc. 1700 Bathgate Ave. Bronx, NY 10457	N/A

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* ANDA # 65-049

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY:
Clindamycin Phosphate Pledgets, 1%	None

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME (If any)
None	None

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Pledgets (Soaked Pads in Jar)	1%	Topical

(PROPOSED) INDICATION (S) FOR USE:
Indicated in the treatment of Acne Vulgaris

APPLICATION INFORMATION

APPLICATION TYPE
(check one) ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug	Holder of Approved Application
Cleocin T® (Solution; Topical)	Pharmacia & Upjohn

TYPE OF SUBMISSION
(check one) ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
Telephone Amendment

PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED One (1) THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment

Cross References (list related License Application, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

ANDA # 65-049

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
×	4. Chemistry section
×	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDAes request)
	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))
	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
	12. Case reports forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C 355 (b) (2) or (j) (2) (A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
×	17. Field-copy certification (21 CFR 314.50 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12
6. Regulations on reports in 21 CFR 314.80,314.81, 600.80 and 600.81
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
	Candis Edwards, Director of Regulatory Affairs	05/23/00

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
Clay-Park Labs, Inc. 1700 Bathgate Ave. Bronx, NY 10457	(718) 960-9976

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a Person is not required to respond to, a collection of Information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address.

ATTACHMENT TO FORM 356h FOR ANDA ESTABLISHMENT INFORMATION

MANUFACTURING, PACKAGING AND CONTROL SITES FOR DRUG PRODUCT

Address:
Clay-Park Labs, Inc.
1700 Bathgate Avenue
Bronx, NY 10457

Contact Person:
Candis Edwards
Director of Regulatory Affairs
Tel: (718) 960-9976
Fax: (718) 960-0111

Establishment Registration #: **2450054**

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

May 23, 2000

Mark Anderson
Food and Drug Administration
Office of Generic Drugs, CDER
Division of Labeling and Program Support
Document Control Room
Metro Park North 2, HFD-617
7500 Standish Place
Rockville, MD 20855

ORIG AMENDMENT

NDA

Re: Telephone Amendment to ANDA # 65-049, Clindamycin Phosphate Pledgets, 1%

Dear Mr. Anderson:

As per our telephone conversations on May 15 and May 23, 2000, Clay-Park Labs, Inc. hereby provides the USP<661> physicochemical – plastic test results performed on the pads (**Attachment 1**), as requested. The results of the test meet the requirements of USP<661> and demonstrate that the pads are safe for use in our Clindamycin Phosphate Pledgets, 1%, drug product.

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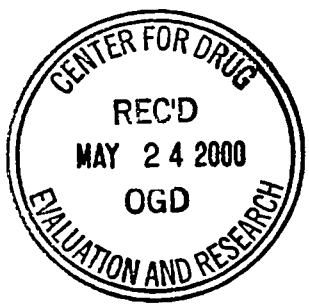
Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Sincerely,

Candis Edwards
Director of Regulatory Affairs



CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

CERTIFICATION

This is to certify that the field copy of the telephone amendment to ANDA # 65-049, dated May 23, 2000, for Clindamycin Phosphate Pledgets, 1% is a true copy of the original submission to the FDA. The field copy has been forwarded to the local New York District Office for their reference.

Candis Edwards
Director of Regulatory Affairs
Clay-Park Labs, Inc.

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

March 24, 2000

NEW CORRESP
NC to FA

Mark Anderson
Food and Drug Administration
Office of Generic Drugs, CDER
Division of Labeling and Program Support
Document Control Room
Metro Park North 2, HFD-617
7500 Standish Place
Rockville, MD 20855

FAX AMENDMENT

Re: ANDA # 65-049 Clindamycin Phosphate Pledgets, 1%

Dear Mr. Anderson:

In reference to the CMC fax deficiency letter dated March 20, 2000 **(Attachment 1)** on our response to the minor amendment for Clindamycin Phosphate Pledgets, 1%, ANDA # 65-049, Clay-Park Labs, Inc. hereby submits the deficiency letter response, designated as a Fax Amendment.

Furthermore, based on our telephone conversation with Mark Anderson, Project Manager and Maria Shih, Chemistry Reviewer on 3/21/00, we agreed that the update to the electronic submission is for informational purposes. The electronic submission will be submitted as a separate correspondence within 30 days.

Should you have any comments or require any further clarifications on this amendment, please contact the undersigned as follows:

Telephone: 718-960-9976 **Fax: 718-960-0111**

Sincerely,

Candis Edwards
Director of Regulatory Affairs

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAR 27 2000
OGD

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

ORIG AMENDMENT

February 4, 2000

Mark Anderson
Food and Drug Administration
Office of Generic Drugs, CDER
Division of Labeling and Program Support
Document Control Room
Metro Park North 2, HFD-617
7500 Standish Place
Rockville, MD 20855

m Anderson 2/17/00

MAJOR AMENDMENT

Re: ANDA # 65-049 Clindamycin Phosphate Pledgets, 1%

Dear Mr. Anderson:

In reference to the deficiency letter dated January 18, 2000 **(Attachment 1)** on our Abbreviated New Drug Application for Clindamycin Phosphate Pledgets, 1%, ANDA # 65-049, Clay-Park Labs, Inc. hereby submits the deficiency response for Chemistry and Labeling sections, designated as a Major Amendment.

Based on our review of the FDA's observations, Clay-Park Labs, Inc. respectfully requests the FDA to redesignate this Major Amendment to a Minor or Fax Amendment, as deemed appropriate, for the following reasons:

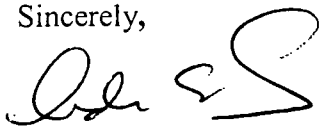
1) **The information required to respond to three (3) out of ten (10) of the observations were contained in the original application, and is being resubmitted in this response for ease of FDA review. (Comment #s 1, 5 and 7)**
2) **The remaining observations required a simple explanation for clarification/correction and did not require submission of any significant new data which would require a review time of over one hour from an experienced chemistry reviewer.**
3) **All deficiencies are within immediate control of Clay-Park Labs, Inc.**
4) **Clay-Park Labs, Inc. was able to respond to the deficiency letter within thirty (30) days.**

Clay-Park Labs, Inc. will submit CMC ESD electronic submission (diskettes) for the major amendment to ANDA # 65-049 for Clindamycin Phosphate Pledgets, 1% as a new correspondence within the 30 day period to update the electronic submission.

Should you have any comments or require any further clarifications on this amendment, please contact the undersigned as follows:

Telephone: 718-960-9976 **Fax: 718-960-0111**

Sincerely,



Candis Edwards
Director of Regulatory Affairs

CLAY-PARK LABS, INC.

AGIS GROUP

1700 BATHGATE AVE. BRONX, NY 10457 (718)901-2800

June 24, 1999

505
(j)(2)(A)(i) Pkt.
Paul Patel

Douglas Sporn
Food and Drug Administration
Office of Generic Drugs, CDER
Document Control Room
Metro Park North II, HFD-600
7500 Standish Place, Room 150
Rockville, MD 20855

Re: ANDA for Clindamycin Phosphate Pledgets, 1%

Dear Mr. Sporn:

Clay-Park Labs, Inc. hereby submits an original abbreviated new drug application (ANDA) in hard copy format to be followed by electronic format, to seek approval to market Clindamycin Phosphate Pledgets, 1% that is bioequivalent to the listed drug, Cleocin T® (Solution; Topical), manufactured by Pharmacia & Upjohn pursuant to NDA # 050537.

This ANDA consists of four (4) volumes. Clay-Park Labs, Inc. is filing an archival copy (in blue folders) of the ANDA that contains all the information required in the ANDA and a technical review copy (in red folders) that contains all the information in the archival copy with the exception of the bioequivalence section (VI). A separate copy of the bioequivalence section is provided in orange folders.

This also certifies that, concurrently with the filing of this ANDA, a true copy of the technical sections of the ANDA (including a copy of the 356h form and a certification that the contents are a true copy of those filed with the Office of Generic Drugs) was sent to our local district office. This "field copy" is contained in burgundy folders.

For more detailed information on the rationale of this ANDA submission and organization of this ANDA, please refer to the "Executive Summary", attached after the field copy certification statement.

Clay-Park Labs, Inc. will submit CMC electronic submission ESD for Clindamycin Phosphate Pledgets, 1% within the 30 day grace period.

Should you have any comments or require any further clarification on this ANDA, please contact the undersigned as follows:

Telephone: (718) 960-9976 **Fax: (718) 960-0111**

Thank you for your prompt handling of this submission.

Sincerely,

Candis Edwards
Director of Regulatory Affairs

Clindamycin Phosphate Pledgets
1% (Topical;Solution)
ANDA 65-049
Reviewer: Moheb H. Makary
W 65049W.699

Clay Park Lab, Inc
Bronx, New York
Submission Date:
June 24, 1999

Review of a Waiver Request

I. Objective:

The firm submitted a full ANDA for the approval of Clindamycin Phosphate Pledgets, 1%. This application was previously submitted to the FDA on April 29, 1999 as supplement 003 to its currently approved ANDA #64-050 (approval dated November 1995) for Clindamycin Phosphate Topical Solution, 1%. As requested by the Agency, the firm submitted the application as a separate full ANDA in order to obtain approval to market the Pledgets.

Clindamycin phosphate is prescribed for the treatment of acne vulgaris.

The firm is requesting a waiver of *in vivo* bioequivalence requirements for its Clindamycin Phosphate Pledgets, 1%, based on CFR 320.22(b)(3).

II. Formulations:

The formulations of the test and the reference products are shown below:

	Clay-Park Labs	Pharmacia & Upjohn
Ingredient	% W/W	Potency
Clindamycin Phosphate,		
Isopropyl Alcohol		
Sodium Hydroxide		
Propylene Glycol		
Water		

III. comments:

1. The test drug meets the criteria for waiver of the *in vivo* bioequivalence study requirements set forth in CFR 320.22(b)(3):

   a. The test product is a solution for application to the skin.

   b. It contains an active drug moiety in the same concentration as a drug product that is the subject of an approved full NDA.

   c. It does not contain any inactive ingredient or change in formulation from the RLD that may significantly affect absorption of clindamycin phosphate.

2. The waiver request of the test drug is granted per 21 CFR Section 320.22(b)(3).

3. Each Cleocin T^{R} Topical Solution pledget applicator contains approximately 1 mL of topical solution.

IV Recommendation:

The Division of Bioequivalence agrees that the information submitted by Clay Park Lab, Inc. demonstrates that Clindamycin Phosphate Pledgets Topical Solution, 1%, falls under 21 CFR section 320.22 (b)(3) of the bioavailability/Bioequivalence regulations. The waiver of *in vivo* bioequivalence study for 1% Clindamycin Phosphate Pledgets Topical Solution of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test topical solution formulation to be bioequivalent to Cleocin^{R} Pledgets Topical Solution, 1%, manufactured by Pharmacia & Upjohn.

The firm should be informed of the above recommendation.

Moheb H. Makary

Moheb H. Makary, Ph.D.
Division of Bioequivalence
Review Branch III

RD INITIALLED BDAVIT BMD 8/11/99
FT INITIALLED BDAVIT Barbara M Davit Date: 8/11/99

Concur: Dale P. Conner Date: 8/12/99

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

Mmakary/8-9-99, 8-12-99, 65049W.699