- Auxiliary stability study 091, month 18 stability tables and interim report. A copy of the protocol and all protocol amendments to date has also been included for reference.

The results obtained to date from the stability studies substantiate the proposed expiry dating [redacted] for the drug product in all three fill sizes, 7.5 g, 42 g, 77 g when stored at controlled room temperature between 15° - 25°C (59° - 77°F).

Reference is also made to CMC volume 1.4, page 002. The following updated packaging components DMF letters are included, which are addressed [redacted]

[redacted]

[redacted]

•

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

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 last page.

FOR FDA USE ONLY
APPLICATION NUMBER

LICANT INFORMATION

NAME OF APPLICANT
Clindagel, LLC

DATE OF SUBMISSION
April 28, 2000

TELEPHONE NO. *(Include Area Code)*
(707) 793-2600

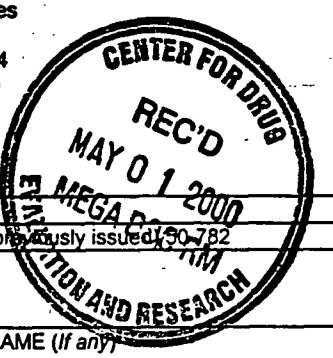
FACSIMILE (FAX) Number *(Include Area Code)*
(707) 793-0145

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:

4189 Chaparral Court
Santa Rosa, CA 95409

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

Robert J. McCormack, Ph.D.
Target Research Associates
554 Central Avenue
New Providence, NJ 07974
Telephone: 908-464-7500
Fax: 908-464-3529



PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 50-782

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)
1% Clindamycin Phosphate, USP

PROPRIETARY NAME (*trade name*) IF ANY
Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)
Clindamycin 2-(dihydrogen phosphate)

CODE NAME (*If any*)

DOSAGE FORM:
Topical gel

STRENGTHS:
1% clindamycin phosphate

ROUTE OF ADMINISTRATION:
Topical

(PROPOSED) INDICATION(S) FOR USE:
Once a day treatment of acne vulgaris

LICATION 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

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
Submission of updated stability data

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

NUMBER OF VOLUMES SUBMITTED 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 this 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 Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment

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)
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	17.	Field copy certification (21 CFR 314.5 (k) (3))
	18.	User Fee Cover Sheet (Form FDA 3397)
X	19.	OTHER (Specify) Submission of updated stability data

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.
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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
Robert J McCormack Ph	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	April 28,2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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Paperwork Reduction Project (0910-0338)
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200 Independence Avenue, S.W.
Washington, DC 20201

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(F)

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

2

TARGET RESEARCH ASSOCIATES

CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

April 26, 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

NDA ORIG AMENDMENT

RE: NDA 50-782
Clindagel, LLC, Santa Rosa, CA
Clindagel™ (Clindamycin Phosphate [redacted] l gel), 1%
Indication: Once a day treatment of acne vulgaris
NDA amendment – submission of dermal absorption study report

BZ

Dear Dr. Wilkin:

Reference is made to NDA 50-782, for Clindagel™ (Clindamycin Phosphate [redacted] gel), 1% for the once a day treatment of acne vulgaris which was submitted on January 27, 2000 and to the commitment, made by Clindagel, LLC, which appears in Vol. 1.1 page 019 and Vol. 1.17 page 002 of the original application.

[In the above referenced commitment statement, Clindagel, LLC, agreed to submit within 3 months of filing the NDA, an amendment containing the final report of the dermal absorption study requested by FDA at the pre-NDA meeting.]

Therefore, on behalf of Clindagel, LLC, we are submitting in duplicate, the final report for study CGEL-005 entitled " An Open-Label Randomized Study of the Comparative Absorption of Clindagel™ (QD) versus Cleocin T (BID) in Subjects with Acne Vulgaris". In addition, we are also submitting an updated package insert, human pharmacokinetic and bioavailability summary and clinical pharmacology summary which incorporate the results obtained from the CGEL-005 study.

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Pharm

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

ORIGINAL

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • FAX: 908/464-7515

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 last page.

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT
Clindagel, LLC

DATE OF SUBMISSION
April 26, 2000

TELEPHONE NO. *(Include Area Code)*
(707) 793-2600

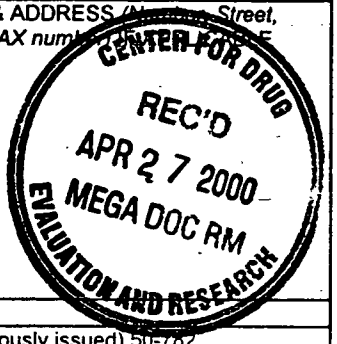
FACSIMILE (FAX) Number *(Include Area Code)*
(707) 793-0145

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:

4189 Chaparral Court
Santa Rosa, CA 95409

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX numbers)*:

Robert J. McCormack, Ph.D.
Target Research Associates
554 Central Avenue
New Providence, NJ 07974
Telephone: 908-464-7500
Fax: 908-464-3529



PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 50-782

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)
1% Clindamycin Phosphate, USP

PROPRIETARY NAME (*trade name*) IF ANY
Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)
Clindamycin 2-(dihydrogen phosphate)

CODE NAME (*If any*)

DOSAGE FORM:
Topical gel

STRENGTHS:
1% clindamycin phosphate

ROUTE OF ADMINISTRATION:
Topical

(PROPOSED) INDICATION(S) FOR USE:
Once a day treatment of acne vulgaris

APPLICATION INFORMATION

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Name of Drug Holder of Approved Application

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☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY, MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
Submission of additional study results and updated technical data sections (Labeling, Clinical Pharmacology, Pharmacokinetics/Bioavailability)

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

NUMBER OF VOLUMES SUBMITTED 4

THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

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x	8.	Clinical data section (e.g. 314.50 (d) (5), 21 CFR 601.2)
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	18.	User Fee Cover Sheet (Form FDA 3397)
	19.	OTHER (Specify)

CERTIFICATION

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

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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Robert J McCormack Ph.D.	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	April 26,2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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Please **DO NOT RETURN** this form to this address.

FORM FDA 356h (4/97)

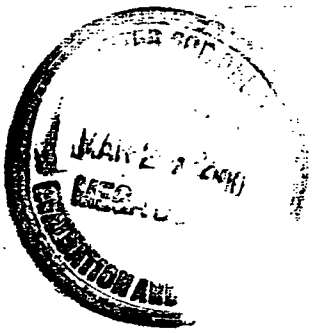
(G)

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

2p

TARGET RESEARCH ASSOCIATES

CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS



March 24, 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: NDA 50-782
Clindagel, LLC, Santa Rosa, CA
Clindagel™ (Clindamycin Phosphate ——— gel), 1%
Indication: Once a day treatment of acne vulgaris
Request for additional information

Dear Dr. Wilkin:

Reference is made to NDA 50782, for Clindagel™ (Clindamycin Phosphate ——— l gel), 1% for the once a day treatment of acne vulgaris submitted on January 27, 2000, and the March 21, 2000 telephone request of Ms. Indira Kumar.

On behalf of Clindagel, LLC, we are submitting in duplicate the following information requested by Ms. Kumar on behalf of the reviewing statistician:

- An electronic version of the Phase III Integrated Clinical and Statistical Report (CGEL-003) in version Word 97
- A diskette labeled CGEL-003 Data Files which contains one zipped file of data in SAS for Windows v. 6.12
- A diskette labeled CGEL-003 Table and Listing Programs which contains one zipped file of programs in SAS for Windows v.6.12
- A copy of the statistical analysis plan for the CGEL-003 study

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

ORIGINAL

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • FAX: 908/464-7515

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
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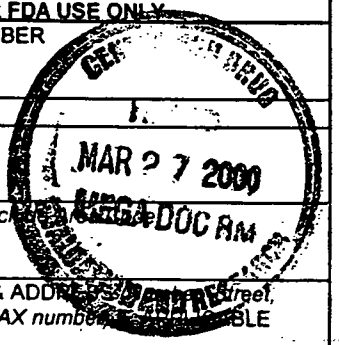

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Clindagel, LLC	March 24, 2000
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(707) 793-2600	(707) 793-0145

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
4189 Chaparral Court Santa Rosa, CA 95409	Robert J. McCormack, Ph.D. Target Research Associates 554 Central Avenue New Providence, NJ 07974 Telephone: 908-464-7500 Fax: 908-464-3529

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 50-782

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)	PROPRIETARY NAME (*trade name*) IF ANY
1% Clindamycin Phosphate, USP	Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)	CODE NAME (*If any*)
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DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
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(PROPOSED) INDICATION(S) FOR USE:
Once a day treatment of acne vulgaris

APPLICATION INFORMATION

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REASON FOR SUBMISSION
FDA request for additional information

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

NUMBER OF VOLUMES SUBMITTED N/A

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	18. User Fee Cover Sheet (Form FDA 3397)
X	19. OTHER (Specify) FDA request for additional information

CERTIFICATION

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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.

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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
Robert J McCormack Ph.D.	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	March 24,2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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

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14 pages

TARGET RESEARCH ASSOCIATES

CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

February 29, 2000

NEW CORRESP

NC

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: Clindagel, LLC, Santa Rosa, CA
Clindagel™ (Clindamycin Phosphate ——— gel), 1%
Indication: Once a day treatment of acne vulgaris
Request for additional information

Dear Dr. Wilkin:

Reference is made to NDA ———, for Clindagel™ (Clindamycin Phosphate ——— , gel), 1% for the once a day treatment of acne vulgaris submitted on January 27, 2000, and the February 28, 2000 telephone request of Ms. Kalyani Bahatt on behalf of Dr. James Vidra.

On behalf of Clindagel, LLC, we are amending ——— to include the statement that ——— clindamycin phosphate has indicated ——— This statement was inadvertently omitted in the original NDA submission. The 356h establishment information has been corrected to reflect the addition ———

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

ORIGINAL

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • FAX: 908/464-7515

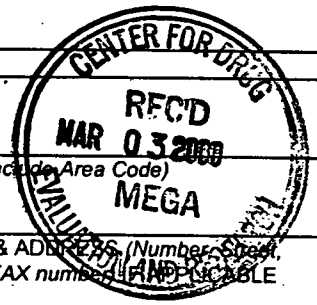
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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 last page.

FOR FDA USE ONLY
APPLICATION NUMBER



APPLICANT INFORMATION

NAME OF APPLICANT
Clindagel, LLC

DATE OF SUBMISSION
February 29, 2000

TELEPHONE NO. *(Include Area Code)*
(707) 793-2600

FACSIMILE (FAX) Number *(Include Area Code)*
(707) 793-0145

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:

4189 Chaparral Court
Santa Rosa, CA 95409

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX numbers)* IF APPLICABLE

Robert J. McCormack, Ph.D.
Target Research Associates
554 Central Avenue
New Providence, NJ 07974
Telephone: 908-464-7500
Fax: 908-464-3529

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)
1% Clindamycin Phosphate, USP

PROPRIETARY NAME (*trade name*) IF ANY
Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)
Clindamycin 2-(dihydrogen phosphate)

CODE NAME (*If any*)

DOSAGE FORM:
Topical gel

STRENGTHS:
1% clindamycin phosphate

ROUTE OF ADMINISTRATION:
Topical

(PROPOSED) INDICATION(S) FOR USE:
Once a day 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

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
FDA request for additional information

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

NUMBER OF VOLUMES SUBMITTED N/A

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 this 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 Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment

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 FDA's 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. 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)
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	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.5 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
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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
Robert J. McCormack, Ph.D.	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	February 29, 2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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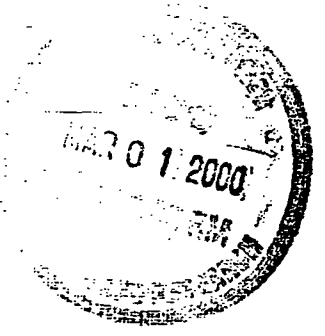
TARGET
RESEARCH
ASSOCIATES

CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

February 29, 2000

NEW CORRESP
NC



Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: Clindagel, LLC, Santa Rosa, CA
Clindagel™ (Clindamycin Phosphate —— gel), 1%
Indication: Once a day treatment of acne vulgaris
Request for additional information

Dear Dr. Wilkin:

Reference is made to NDA —— for Clindagel™ (Clindamycin Phosphate —— gel), 1% for the once a day treatment of acne vulgaris submitted on January 27, 2000, and the February 29, 2000 telephone request of Ms. Millie Wright.

On behalf of Clindagel, LLC, we are submitting duplicate electronic copies of the annotated and non-annotated Clindagel package insert as requested by Ms. Millie Wright.

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

ORIGINAL

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • FAX: 908/464-7515

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
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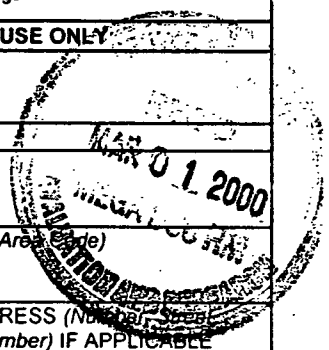

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Clindagel, LLC	February 29, 2000
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(707) 793-2600	(707) 793-0145

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
4189 Chaparral Court Santa Rosa, CA 95409	Robert J. McCormack, Ph.D. Target Research Associates 554 Central Avenue New Providence, NJ 07974 Telephone: 908-464-7500 Fax: 908-464-3529

PRODUCT DESCRIPTION

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ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)	PROPRIETARY NAME (*trade name*) IF ANY
1% Clindamycin Phosphate, USP	Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)	CODE NAME (*If any*)
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DOSAGE FORM:	STRENGTHS.	ROUTE OF ADMINISTRATION:
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Once a day treatment of acne vulgaris

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Name of Drug — Holder of Approved Application

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FDA request for additional information

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3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Robert J McCormack	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	February 29, 2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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(K)

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(K)

(L)

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1 page (L)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

(Division/Office): HFD-520 (Division of Anti Infective Drug Prodcts)			FROM: HFD-540 (Division of Dermatologic and Dental Drug Products) Jonathan Wilkin, MD/Division Director	
DATE: February 2, 2000	IND NO.:	NDA NO.:	TYPE OF DOCUMENT: New NDA Submission	DATE OF DOCUMENT: 1-27-00
NAME OF DRUG: Clindagel (clindamycin phosphate 1% gel)	PRIORITY CONSIDERATION: Standard		CLASSIFICATION OF DRUG: Antibiotic	DESIRED COMPLETION DATE: May 2, 2000

NAME OF FIRM: Clindagel, LLC (US Agent: Target Research Associates)

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE-NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☒ OTHER *(SPECIFY BELOW)*: New NDA Submission

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER:	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER:

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

Attn: Tom Hassel/ADRA/ODE IV
The Division is requesting a microbiology consult for this new NDA submission. When a reviewer is assigned, I will invite you and that reviewer to the filing meeting.
Please let me know if I can be of further asistance. Thanks.
Indira Kumar/Project Manager 301-827-2072

Original NDA
HFD-540/Div. Files
(HFD-540/I. Kumar/J. Vidra/W. DeCamp

SIGNATURE OF REQUESTER: 2-2-00	METHOD OF DELIVERY (Check one): ☒ MAIL ☐ HAND
SIGNATURE OF RECEIVER:	SIGNATURE OF DELIVERER:

CLINDAGEL, LLC.
4189 Chaparral Court • Santa Rosa CA 95409
Phone: (707) 483-7489 • Fax: (707) 546-3058

January 5, 2000

Jonathan K. Wilkin, M.D., Director
Division of Dermatologic and Dental Drug Products (HFD-540)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20875

Re: Clindagel™ (clindamycin phosphate — l gel), 1%

Dear Dr. Wilkin:

Please be advised that Dr. Robert McCormack, V.P. of Regulatory Affairs at Target Research Associates, has been appointed the US Agent and, as such, will act on behalf of Clindagel, LLC with regard to all matters concerning Clindagel™. Henceforward, please address all future communications, including FDA correspondence concerning Clindagel-related matters, directly to Dr. McCormack at the following address:

Robert McCormack, Ph.D.
Target Research Associates, Inc.
554 Central Avenue
New Providence, NJ 07974
Phone: (908) 464-7500
Fax: (908) 464-3529

Sincerely yours,

Gordon J. Dow, Pharm.D.
Managing Member
Clindagel, LLC
Telephone (707) 483-7489
FAX (707) 546-3058

APPEARS THIS WAY
ON ORIGINAL

cc: K. White, B. McCormack

TARGET
RESEARCH
ASSOCIATES

CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

January 27, 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: Clindagel, LLC, Santa Rosa, CA
Clindagel™ (Clindamycin Phosphate — gel), 1%
Indication: Once a day treatment of acne vulgaris
Initial submission of NDA 21-230

Dear Dr. Wilkin:

Pursuant to paragraph 505(b)(2) of the Food, Drug, and Cosmetic Act and 21 CFR 314.50, we are, on behalf of Clindagel LLC, submitting in duplicate a New Drug Application, NDA —, for Clindagel™ (Clindamycin Phosphate — gel), 1% for the once a day treatment of acne vulgaris.

This NDA contains, among other items, a single adequate and well-controlled clinical trial to support the acne vulgaris indication. The protocol design was discussed at both the pre-IND and End of Phase 2 meetings with FDA and evaluated the following treatment groups: Clindagel QD, Clindagel Vehicle QD, Clindagel BID, Clindagel Vehicle BID and Cleocin T BID. The results of the trial were discussed with FDA during the pre-NDA meeting and it was concluded that the data would support the filability of the application.

All of the available information requested at the pre-NDA meeting has been incorporated in the NDA. At the beginning of each technical data section is an introduction which describes the content and format of the section as well as a regulatory summary pertinent to that specific section of the application.

A completed Application to Market a New Drug for Human Use (form FDA 356h) is enclosed. Also enclosed, and agreed to at the pre-NDA meeting, is Clindagel LLC's —

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • FAX: 908/464-7515

A full waiver for submitting Pediatric Use Information has been provided in Volume 1.1. In addition, a completed User Fee Cover Sheet (form 3397) is included. User Fee I.D. 3885 has been assigned to the Clindagel™ NDA, and a check for the amount of $285,740.00 has been transmitted electronically to the Food and Drug Administration at the address of Mellon Bank, Pittsburgh, PA.

This application consists ——— which are numbered consecutively, individually paginated and contains all the information where relevant, as specified in 21 CFR 314.50. We have provided both a complete archival copy (blue binders) and a review copy of the volumes. Also, as requested by FDA, we will be providing 15 additional desk copies of Volume 1.1 so that they can be supplied to supervisory personnel and the reviewers of each NDA Technical Data Section. The binders are color-coded to represent each technical data section. These additional copies will be sent directly to Ms. Sandy Childs within a couple of days.

After following the advice of the Division of Dermatologic and Dental Drug Products, we believe this Application to be complete for review by your staff and would look forward to discussing, informally, the status of your review in approximately 45 days.

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.
Vice President, Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL

(X)

Number of Pages Redacted 2

❖❖❖

Confidential,
Commercial Information

(X)

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 last page.

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Clindagel, LLC	January 27, 2000
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(707) 793-2600	(707) 793-0145

APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*:

4189 Chaparral Court
Santa Rosa, CA 95409

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

Robert J. McCormack, Ph.D.
Target Research Associates
554 Central Avenue
New Providence, NJ 07974
Telephone: 908-464-7500
Fax: 908-464-3529

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)	PROPRIETARY NAME (*trade name*) IF ANY
1% Clindamycin Phosphate, USP	Clindagel

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)	CODE NAME (*If any*)
Clindamycin 2-(dihydrogen phosphate)	

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Topical gel	1% clindamycin phosphate	Topical

PROPOSED) INDICATION(S) FOR USE:
Once a day 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

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
Original NDA

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

NUMBER OF VOLUMES SUBMITTED —

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 this 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 Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See Attachment

This application contains the following items: *(Check all that apply)*		
X	1.	Index
X	2.	Labeling (check one) ☒ Draft Labeling ☐ Final Printed Labeling
X	3.	Summary (21 CFR 314.50 (c))
X	4.	Chemistry section
X		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 FDA's request)
X		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
X	5.	Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
X	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))
X	8.	Clinical data section (e.g. 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)
X	10.	Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
X	11.	Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
X	12.	Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
X	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)
X	16.	Debarment certification (FD&C Act 306 (k)(1))
X	17.	Field copy certification (21 CFR 314.5 (k) (3))
X	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
Robert J McCormack/dp	Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs Target Research Associates	January 27, 2000

ADDRESS (*Street, City, State, and ZIP Code*)	Telephone Number
Target Research Associates 554 Central Avenue New Providence, NJ 079747	(908) 464-7500

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.

(M)

Number of Pages Redacted 9+12=21

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FILING MEETING PM CHECKLIST

NDA: 50-782 Clindagel (clindamycin phosphate ~~2~~ gel) 1%

Indication: Once a day treatment of acne vulgaris

Sponsor: Clindagel, LLC (US Agent: Target Research Associates)

Meeting: March 6, 2000 9:00am

CDER Stamp Date: January 27, 2000
Primary Goal Date (10 Month): November 27, 2000
Secondary Goal Date (12 month): December 27, 2000
Filing Date: March 27, 2000

FILEABILITY: Initial overview of the NDA application:

PROJECT MANAGEMENT:

1. Do any of the following apply to this application (i.e., if YES , the application MUST BE REFUSED TO FILE under 314.101 (e) and there is no filing over protest):

   a. Is the drug product already covered by an approved application? No.

   b. Does the submission purport to be an abbreviated application under 314.55; however the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under 314.55(b)? No.

   c. Is the drug product subject to licensing by FDA under the Public Service Act and Subchapter F of Chapter I of Title 21 of the CFR? No.

2. Do any of the following apply to this application (i.e., if NO, the application MAY BE REFUSED TO FILE under 314.101(d) and there is the potential for filing over protest):

   a. Does the application contain a completed application form as required under 314.50 or 314.55? Yes.

   b. On its face, does the application contain the sections of an application required by regulation and Center guidelines? Yes.

   c. Has the applicant submitted a complete environmental assessment, which addresses each of the items, specified in the applicable format under 25.31 or has the applicant submitted evidence to establish that the product is under 25.24 of the CFR? Volume 1.5, page 26.

(N)

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

4 pages

THIS SECTION
WAS
DETERMINED
NOT
TO BE
RELEASABLE

20 pages

AUG 2 8 2000

MEMORANDUM OF TELECON

DATE: August 23, 2000 11:30am

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate [redacted] gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs
Andy Lawson
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Dennis Bashaw, Ph.D./Biopharm Team Leader
Abi Adebowale, Ph.D./ Biopharm Reviewer
Lisa Mathis, M.D./Medical Reviewer
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Clarification of the urinary excretion data

The biopharm reviewer wanted to clarify the treatment of the urinary excretion data for study CGEL-005 included in the submission for NDA 50-782 and, how the results were expressed in the proposed label for clindagel 1%. What the sponsor proposed in t [redacted]

The Division noted that the amount excreted or the percentage of the dose excreted over the time interval (i.e. 24 hours in this case) is the standard way urinary data is usually reported. This is the data that the Division is requesting. The Division indicated that the applicant determined the concentration of an aliquot of urine and that the volume of urine collected should be in the case report forms and, these can then be used to obtain the amount excreted. The Division would like to see this data and supporting tables and, how it was calculated.

The applicant representative noted that they would have to re-do the statistical test and that they would have to go back to the data and convert concentration to amount of clindamycin in the urine.

The Division inquired as to a timeframe when this data would be submitted for review.

The applicant representative stated that they would be in touch with the Division later today with a timeline.

/S/
Indira Kumar/Project Manager

/S/
Abimbola Adebowale, Ph.D./Biopharm Reviewer

Indira Kumar

AUG 17 2000

MEMORANDUM OF TELECON

DATE: August 17, 2000 11:45am

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate —— gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Abi Adebowale, Ph.D./ Biopharm Reviewer
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Clarification of the urinary excretion data

The biopharm reviewer wanted clarification between the urinary excretion data submitted in the original submission, volume 1, page 14, Table 6 and the fax of 8-16-00. The biopharm reviewer was requesting a telecon between the biopharm scientist of Target Research & LLC and the FDA reviewers (Team leader and herself).

The applicant representative agreed to schedule a telecon and would get back to the FDA with available times on 8-18-00. She noted that if she had an answer by or before the telecon, she would send that to the Division as well.

/S/

Indira Kumar/Project Manager

cc: Original NDA 50-782
HFD-540/Div. File
HFD-540/Indira Kumar/Project Manager
HFD-540/A. Adebowale/ D. Bashaw

APPEARS THIS WAY
ON ORIGINAL

TELECON

I. Kumar

JUL 11 2000

MEMORANDUM OF TELECON

DATE: July 11, 2000 3:10pm

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate —— gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Abi Adebowale, Ph.D./ Biopharm Reviewer
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Information request for Biopharm

The biopharm reviewer requested a table of the pharmacokinetic variable/AUC for each patient for urine and plasma that was used in the statistical analysis for both clindamycin and cleocin.

The sponsor representative said that she would submit the information in both electronic and paper format as soon as possible.

/S/

Indira Kumar/Project Manager

APPEARS THIS WAY
ON ORIGINAL

cc: Original NDA 50-782
HFD-540/Div. File
HFD-540/Indira Kumar/Project Manager
HFD-540/A. Adebowale

TELECON

I. Kumar

MEMORANDUM OF TELECON

DATE: March 30, 2000 2:00 pm

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate ——— gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Electronic data clarification.

Statistical:

SAS data sets, programs (SAS version 6.12), transport files are okay.

Sponsor representative sent data 3/24/00

The format the Pharmacology/ Dermal carcinogenicity data should be in SAS data, transport files, analysis and a Word description of the data.

The sponsor representative said that she was planning to submit that data in that format.

/S/
Indira Kumar/Project Manager

cc: Original NDA 50-782
HFD-540/Div. File
HFD-540/Indira Kumar/Project Manager

APPEARS THIS WAY
ON ORIGINAL

TELECON

MEMORANDUM OF TELECON

DATE: March 21, 2000 9:40am

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate —— gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: NDA number and electronic data.

The Division wanted to inform the company that the NDA number has changed from —— to 50-782 because this product is an antibiotic approved prior to FDAMA therefore it retains the 50K number series.

There were several requests for electronic data sets from several reviewers per the filing meeting:

Statistical:

SAS data sets, programs (SAS version 6.12), and "Clinical Data summary and results of the statistical analysis" in electronic format (Microsoft Word).

Also the Final Study Report of the Phase 3 study in electronic format (Microsoft Word).

Pharmacology/Toxicology:

Dermal carcinogenicity data and analysis electronically by the end of March.

The sponsor representative can get us the Statistical data by the week of March 27, 2000 and the Pharmacology data by the week of April 10, 2000.

PM to follow up on exactly what format should the Pharmacology/ Dermal carcinogenicity data be in.

/S/
Indira Kumar/Project Manager

MEMORANDUM OF TELECON

DATE: 2-1-00 1:25am, 3:40pm

APPLICATION NUMBER: NDA ——— Clindagel 1% (clindamycin phosphate ——— gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.
Phone: 908-464-7500
Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: User Fee Payment

The Division wanted to know if the user fee was paid and when.

The sponsor representative noted that the user fee should have been wired January 18 or 19, 2000. She will verify with Clindagel, LLC in California today at 11:00am and contact the Division as soon as she has word of the funds.

She also verified that the Division, last week, received 15 desk copies of the 1.1 volume of the NDA.

I introduced myself as the Project Manager of this new NDA and asked that all communications go through me.

3:40pm

Jill Powers called to follow up on the User Fee issue. She noted that Clindagel, LLC wired the funds January 28, 2000 and the confirmation number is ——— She will be faxing this information to the Division today.

[/S/] 2-1-00

Indira Kumar/Project Manager

cc: Original NDA ———
HFD-540/Div. File
HFD-540/Indira Kumar/Project Manager

TELECON

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

NDA/PLA/PMA # 50-782 Supplement # _____ Circle one: SE1 SE2 SE3 SE4 SE5 SE6

-540___ Trade and generic names/dosage form: Clindagel (clindamycin phosphate) topical gel, 1% Action: AP AE NA

Applicant Clindagel, LLC (Target Research Associates) Therapeutic Class 3S

Indication(s) previously approved Treatment of acne vulgaris

Pediatric information in labeling of approved indication(s) is adequate _X_ inadequate __

Proposed indication in this application Treatment of acne vulgaris

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.

IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS? _X_ Yes (Continue with questions) ___ No (Sign and return the form)
WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)
___Neonates (Birth-1month) ___Infants (1month-2yrs) __Children (2-12yrs) _X_Adolescents(12-16yrs)

___ 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.

_X_ 2. **PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

__ 3. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use.
- ___a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.
- __ b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.
- __ c. The applicant has committed to doing such studies as will be required.
  - ___ (1) Studies are ongoing,
  - ___ (2) Protocols were submitted and approved.
  - ___ (3) Protocols were submitted and are under review.
  - ___ (4) If no protocol has been submitted, attach memo describing status of discussions.
- ___ d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

___ 4. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

___ 5. **If none of the above apply,** attach an explanation, as necessary.

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER? ___ Yes _X_ No
ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from X (Medical Review/Medical Team Leader (e.g., medical review, medical officer, team leader).

/S/
Jonathan K. Wilkin, M.D./Division Director, HFD-540 — Date 11/19/00

/S/
Indira Kumar/ Regulatory Project Manager, HFD-540 — Date 11/19/00

Archival NDA 50-782, HFD-540/Div File
HFD-540/Wilkin/Kumar/Walker-Hunt/Action Package
HFD-104/Peds/T.Crescenzi

(revised 3/6/00)

Pediatric Use Information

In accordance with 21 CFR 314.55(c)(2)(ii) we are hereby requesting a full waiver from supplying Pediatric Use Information for Clindagel in the treatment of acne. A full waiver is being requested since the number of patients available with pediatric acne is so small, it makes the necessary studies highly impractical to conduct in a reasonable period of time.

1/4/00

Gordon Dow, PharmD
Clindagel, LLC

APPEARS THIS WAY
ON ORIGINAL