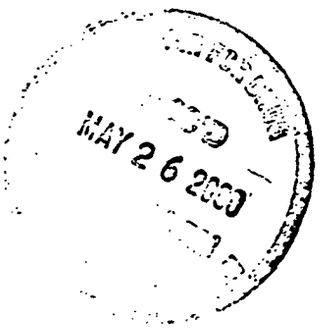
500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107
TEL. 610-454-8000

NDA ENDORSEMENT

May 25, 2000



Jonathan K. Wilkin, M.D., Director
Division of Dermatologic and Dental
Drug Products
Center for Drug Evaluation and Research
Office of Drug Evaluation V
Food and Drug Administration
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

ORIGINAL

S4

NDA #50-769
Benzamycin®
(3% erythromycin and 5% benzoyl peroxide gel)

Safety Update Report

Dear Dr. Wilkin:

Our New Drug Application for Benzamycin® was submitted to the Food and Drug Administration January 26, 2000. Therefore, the submission of a 120 day (4 month) Safety Update Report is required on or before May 26, 2000. This letter serves as a Safety Update Report for our Benzamycin application.

Please be informed that no clinical trials have been conducted with Benzamycin that were not included in the original NDA submission. Therefore, there is no additional clinical study safety information to provide at this time. Additionally, Dermik is not aware of any other safety information that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions included in the draft labeling submitted in our original application.

We believe this submission fully responds to the safety update requirement. If you have any questions or require any additional information, please contact me at (610) 454-3027.

Sincerely yours,

James P. Thompson

James P. Thompson
Manager
Worldwide Regulatory Affairs

JPT/maf
Enclosures

DERMIK LABORATORIES, INC.
Dedicated to Dermatology™
A RHÔNE-POULENC RORER COMPANY

500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107
TEL. 610-454-8000

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUN 12 2000
MEGA DOC RM

June 8, 2000

Jonathan K. Wilkin, M.D., Director
Division of Dermatologic and Dental
Drug Products
Center for Drug Evaluation and Research
Office of Drug Evaluation V
Food and Drug Administration
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

NEW CORRESP
NC

NDA #50-769
Benzamycin®
(3% erythromycin and 5% benzoyl peroxide gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to a May 31, 2000 telephone call Dermik received from Commander Frank Cross, Jr. requesting the submission of the application summary and clinical information included in the original NDA submission for Benzamcyin® on computer disks in Microsoft Word.

Included in this submission are the disks Commander Cross requested.

If you have any questions or require any additional information, please contact me at (610) 454-3027.

Sincerely yours,

James P. Thompson

James P. Thompson
Manager
Worldwide Regulatory Affairs

JPT/maf
Enclosures

Desk Copy: Brenda E. Vaughan, Medical Officer

ORIGINAL

DERMIK LABORATORIES, INC.
Dedicated to Dermatology
A RHÔNE-POULENC RORER COMPANY

500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107
TEL. 610-454-8000

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUL 27 2000
MEGA

July 25, 2000

AMENDMENT
BL

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
Attention: Document Control Room
9201 Corporate Boulevard
Rockville, MD 20850

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% topical gel)

Proposed Change of the Product Name Modifier

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® (erythromycin 3% and benzoyl peroxide 5% topical gel). The NDA contained proposed draft labeling for Benzamycin®.

In the original NDA we had proposed the name [redacted] a modifier of the tradename Benzamycin®. In this submission, we are proposing the replacement of [redacted] th the name "Pak" as a modifier of the Benzamycin tradename. Therefore, the proposed new tradename for our unit dose dual pouch erythromycin and benzoyl peroxide product is Benzamycin® Pak.

At this time, we are proposing no further changes to the labeling included in our original NDA.

Thank you for your attention. Please contact me at (610) 454-3027 if you have any questions.

Sincerely,

James P. Thompson

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

ORIGINAL

DERMIK LABORATORIES, INC.
A RHÔNE-POULENC RORER COMPANY
Dedicated to Dermatology™

500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107
TEL. 610-454-8000

NEW CORRES-

CENTER FOR DRUG
REC'D
AUG 0 7 2000
MEGA DOC RM
EVALUATION AND RESEARCH

August 4, 2000

Jonathan K. Wilkin, M.D., Director
Division of Dermatologic and Dental Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

NDA 50-769
Benzamycin® Pak
(erythromycin 3% and benzoyl peroxide 5% topical gel)

CHANGE OF ADDRESS

Dear Dr. Wilkin:

Reference is made to our New Drug Application for Benzamycin® (erythromycin 3% and benzoyl peroxide 5% topical gel).

Please be advised that, effective August 16, 2000, Dermik Laboratories, Inc., the sponsor of the referenced NDA, will move from their Collegeville, Pennsylvania facility to a new facility in Berwyn, Pennsylvania. Our new address is:

Dermik Laboratories, Inc.
1050 Westlakes Drive
Berwyn, PA 19312

Also, please be aware that during a five-day period beginning Friday, August 11, 2000 and ending Tuesday, August 15, 2000, Dermik's office telephones and fax machine will be out of service. However, Ms. Alina Zielinski, a Dermik representative, will be available for telephone calls at (610) 454-3033 and fax messages can be sent to (610) 454-5287.

I will continue to be the primary FDA contact person for Dermik. In addition, Alicia Cabrelli is also authorized as a Dermik contact person. Her telephone number is (484) 595-2775. My new telephone number is (484) 595-2795 and our new fax number is (484) 595-2785.

If you have any questions regarding our relocation or the referenced application, please feel free to contact me at the above listed telephone number.

Sincerely,

James P. Thompson

ORIGINAL

James P. Thompson
Manager, Regulatory Affairs

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

NDA ORIG AMENDMENT

September 26, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

BL

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% topical gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® (erythromycin 3% and benzoyl peroxide 5% topical gel). Additional reference is made to a telephone conversation with Commander Frank Cross, Sr. Regulatory Project Manager, DDDDP, and Dermik's Ms. Alicia Cabrelli on September 26, 2000.

At the request of the medical reviewer, Dr. Brenda Vaughn, Commander Cross requested that a 'clean' copy and a copy with strikethrough and additional highlighted text of the proposed package insert be submitted on diskette, to DDDDP for review. Enclosed on diskette are the following files:

1. *092600-clean* *.Benzamycin® Pak Package Insert (clean copy)*
2. *092600-vers1.* *Benzamycin® Pak Package Insert (strikethrough and additions)*

As per Commander Cross's telephone request, this will confirm that the name Benzamycin® is a registered trademark of Dermik Laboratories, Inc.

In response to Commander Cross' question concerning a Patient Package Insert (PPI) for Benzamycin® Pak, please be informed that we do propose Instructions for Use in the Benzamycin® Pak labeling but we did not include a PPI in the proposed labeling submitted to this application.

Thank you for your attention. Please contact me at (484) 595-2795 if you have any questions.

Sincerely,

James P. Thompson

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

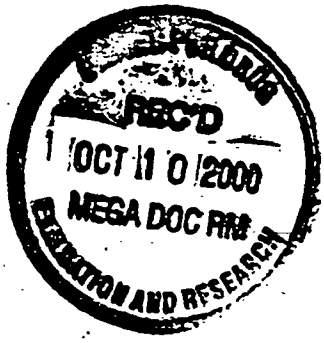
ORIGINAL

cc: Cmdr. Frank Cross, Sr. Regulatory Project Manager- Desk Copy
Encl.

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

NDA ORIG AMENDMENT



October 6, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

BC

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original New Drug Application for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Additional reference is made to a telephone conversation Commander Frank Cross, Sr. Regulatory Project Manager, and Dr. James Vidra, Chemistry Reviewer, DDDDP, had with Dermik's Ms. Alicia Cabrelli on October 4, 2000.

As requested by Dr. Vidra during the telephone conversation, this letter authorizes the Food and Drug Administration to access and incorporate by reference into our New Drug Application for Benzamycin® Pak (NDA 50-769) Chemistry, Manufacturing and Controls information included in Supplement 20 of our approved New Drug Application for Benzamycin® Topical Gel (NDA 50-557).

Thank you for your attention. Please contact me at (484) 595-2795 if you have any questions.

Sincerely,

James P. Thompson

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

ORIGINAL

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

October 13, 2000

NDA ORIG AMENDMENT

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

BC

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Additional reference is made to a telephone conversation Commander Frank Cross, Sr. Regulatory Project Manager, and Dr. James Vidra, Chemistry Reviewer, DDDDP, had with Dermik's Ms. Alicia Cabrelli on October 11, 2000.

The Division requested that additional stability reports for the drug substance benzoyl peroxide for this application be submitted to this application for review by the Division.

The following stability reports are attached:

1. *Three 6-month stability reports for Validation Batch #1, #2, and #3*
2. *One 9-month stability report for Validation Batch #3*
3. *Two 12-month stability reports for Validation Batch #1 and #2*

Thank you for your attention. Please contact me at (484) 595-2795 or Ms. Alicia Cabrelli at (484) 595-2775 if you have any questions.

Sincerely,

James P. Thompson

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

ORIGINAL

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

CENTER FOR DRUG EVALUATION AND RESEARCH
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OCT 30 2000
MEGA DOC RM

October 27, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N229
Rockville, MD 20850

...MENT
BC

NDA #50-769
Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of our original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Reference is also made to a telephone conversation Commander Frank Cross, Sr. Regulatory Project Manager, DDDDP had with Dermik's Mr. James Thompson on October 18, 2000. This conversation was followed-up with a teleconference on October 23, 2000 between representatives of the Division and Dermik (minutes and information requests were provided to Dermik in a fax from Commander Frank Cross on 24 October 2000).

Dermik's responses to the information requested by Dr. James Vidra, Chemist, and by Dr. Brenda Vaughn, Medical Reviewer are provided in this letter.

CHEMISTRY RELATED INFORMATION

The following information was requested by Dr. James Vidra.

1. A reprocessing Statement or a brief summary of any proposed reprocessing procedures covering foreseeable deviations from specifications:

   Dermik Laboratories will not reprocess either Benzoyl Peroxide Gel, Erythromycin Gel or the final packaged product (Benzamycin Pak) without an FDA approved process as proposed in an NDA supplement.

ORIGINAL

3 Pages have been redacted in full from this document

Reason:

_____ b(2) 'low'
__X__ b(4) CCI } FORMULATION TESTING
__X__ b(4) TS
_____ b(5) Deliberative Process:
Attorney Client and Attorney Work Product Privilege
_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
NOV 06 2000
MEGA DOC RM

November 3, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N229
Rockville, MD 20850

BM

NDA #50-769
Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

Response to FDA Request for Information

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of our original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Reference is also made to a telephone conversation Commander Frank Cross, Sr. Regulatory Project Manager, DDDDP had with Dermik's Mr. James Thompson on October 18, 2000. In an official submission on October 27, 2000 to the Division, Dermik stated the following information.

CLINICAL RELATED INFORMATION

The following information was requested by Dr. Brenda Vaughn, Medical Reviewer.

Study DL 6026-9709

1. *Pregnancy outcomes for patients #55 and 64.*
   Dermik has contacted the site and written correspondence should be provided by 1 November 2000. However, verbally the site has communicated to us that patient #55 terminated her pregnancy. The site is currently working to contact patient #64.
   Written correspondence from site is attached.

Thank you for your attention. Please contact me at (484) 595-2775 if you have any questions.

Sincerely,

Alicia Cabrelli

Alicia Cabrelli
Regulatory Analyst

ORIGINAL

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

November 21, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

NDA [illegible] AMENDMENT

BL

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

SPONSOR DRAFT LABELING

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Additional reference is made to Dermik's response to the Division's draft labeling sent via facsimile and electronically on Monday, November 20, 2000 from DDDDP Sr. Project Manager, Commander Frank Cross. Please be advised that the following documents containing Dermik's comments and proposals concerning the labeling proposed by DDDDP were forwarded electronically to Commander Cross and Ms. Olga Cintron on Monday, November 20, 2000 and Tuesday, November 21, 2000.

The following documents are enclosed:

1. *Rationale (The location reference in the Draft1-112000withrevision. for each of the proposed changes, and the reasons for the changes are listed).*
2. *Draft 1-112000withrevision.*
3. *Carton Trade*
4. *Pouch Trade*

Thank you for your attention. Please contact me at (484) 595-2795 if you have any questions.

Sincerely,

James P. Thompson/oc

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

ORIGINAL

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

November 22, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

SPONSOR CONCURRENCE WITH FDA's DRAFT LABELING

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Additional reference is made to Dermik's concurrence of the Divisions' Draft Labeling (package insert, carton and pouch), that was provided by Olga Cintron, R.Ph., Project Manager, via facsimile and electronically on Wednesday, November 22, 2000.

Dermik has reviewed and concurs with the Division's Draft Labeling provided on November 22, 2000.

Thank you for your attention. Please contact me at (484) 595-2775 if you have any questions.

Sincerely,

Alicia Cabrelli

Alicia Cabrelli
Regulatory Analyst
Worldwide Regulatory Affairs

APPEARS THIS WAY ON ORIGINAL

DERMIK LABORATORIES, INC.

1050 WESTLAKES DRIVE
BERWYN, PA 19312
484-595-2700

November 27, 2000

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
9201 Corporate Boulevard
Building No. 2, Second Floor, Room N115
Rockville, MD 20850

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel)

Sponsor's Phase IV Commitment

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% gel). Additional reference is also made to a November 27, 2000 facsimile transmission from DDDDP Sr. Project Manager, Commander Frank Cross, Jr. recommending that Dermik commit to a post-marketing commitment for this NDA.

As recommended in this communication, Dermik commits to the following.

Within 3 months of NDA approval, conduct and report the results of a flammability or flashpoint study on the erythromycin gel since it contains ethyl alcohol.

Thank you for your attention. Please contact me at (484) 595-2775 if you have any questions.

Sincerely,

Alicia Cabrelli

Alicia Cabrelli
Regulatory Analyst
Worldwide 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, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICATION INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Dermik Laboratories, Inc.	November 27, 2000
TELEPHONE NO. *(Include Area Code)*	FACSIMILE (FAX) Number *(Include Area Code)*
(484) 595-2775	(610) 484-595-2785
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
1050 Westlakes Drive Berwyn, PA 19312	

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* NDA 50-769

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
(erythromycin and benzoyl peroxide)	Benzamycin®Pak

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*	CODE NAME *(If any)*
	DL-6026

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Topical Gel	erythromycin 3% and benzoyl peroxide 5%	Topical

(PROPOSED) INDICATION(S) FOR USE: Topical Treatment of acne vulgaris

APPLICATION INFORMATION

APPLICATION TYPE *(check one)* X NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)

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

IF AN ANDA, OR 505(b)(2), 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 ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT X OTHER

IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION Sponsor's Phase IV Commitment

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

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS X PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
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 Original Application

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

NDA 50-557; NDA 50-557 Supplement 20.

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., 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 report 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. Financial Information (21 CFR Part 54)
X	20. OTHER *(Specify) Sponsor's Phase IV Commitment*

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 Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 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 Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 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 knowlegde 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
Alicia Cabrelli	Alicia Cabrelli. Regulatory Analyst Worldwide Regulatory Affairs	November 27, 2000

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
1050 Westlakes Drive Berwyn, PA 19312	(484) 595-2775

Public reporting burden for this collection of information is estimated to average 24 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:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

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.

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO (Division/Office): OPDRA, HFD-400, Sammie Beam, Room klwn 15B08	FROM: HFD-540 (Division of Dermatologic and Dental Drug Products) Frank Cross

DATE:	IND NO.:	NDA NO.:	TYPE OF DOCUMENT:	DATE OF DOCUMENT:
March 20, 2000		50-769	Original NDA	1/26/00

NAME OF DRUG:	PRIORITY CONSIDERATION:	CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE:
Benzamycin	3S	3S	10/27/00

NAME OF FIRM: Dermik Laboratories

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)*:
  Tradename Consult

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: Please review the Applicant's proposed Tradename for this NDA and provide us with your feedback. Thanks, Frank (7-2063)

cc: Original NDA 50-769
HFD-540/Div. Files
HFD-540/Cross

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

FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO (Division/Office): OPDRA, HFD-400, Sammie Beam, Room 15B08			FROM: HFD-540 (Division of Dermatologic and Dental Drug Products) Frank Cross	
DATE: August 4, 2000	IND NO.:	NDA NO.: 50-769	TYPE OF DOCUMENT: Proposed Change of Product Name Modifier	DATE OF DOCUMENT: 7/25/00
NAME OF DRUG: Benzamycin	PRIORITY CONSIDERATION: S		CLASSIFICATION OF DRUG: 3	DESIRED COMPLETION DATE: 10/27/00

NAME OF FIRM: Dermik Laboratories, Inc.

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 Tradename Consult**

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: Please review the Applicant's proposed new Tradename for this NDA and provide us with your feedback. Thanks, Frank (7-2063)

cc: Original NDA 50-769
HFD-540/Div. Files
HFD-540/Cross

SIGNATURE OF REQUESTER:	METHOD OF DELIVERY (Check one): ☒ MAIL ■ HAND
SIGNATURE OF RECEIVER:	SIGNATURE OF DELIVERER:

DERMIK LABORATORIES, INC.
Dedicated to Dermatology
A RHÔNE-POULENC RORER COMPANY

500 ARCOLA ROAD
P.O. BOX 1200
COLLEGEVILLE, PA 19426-0107
TEL. 610-454-8000

CENTER FOR DRUG
REC'D
JUL 27 2000
MEGA
EVALUATION AND RESEARCH

July 25, 2000

AMENDMENT
BL

Jonathan Wilkin, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products (HFD-540)
Attention: Document Control Room
9201 Corporate Boulevard
Rockville, MD 20850

NDA #50-769

Benzamycin® Pak (erythromycin 3% and benzoyl peroxide 5% topical gel)

Proposed Change of the Product Name Modifier

Dear Dr. Wilkin:

Reference is made to our January 27, 2000 submission of an original NDA for Benzamycin® (erythromycin 3% and benzoyl peroxide 5% topical gel). The NDA contained proposed draft labeling for Benzamycin®

In the original NDA we had proposed the name [redacted] as a modifier of the tradename Benzamycin®. In this submission, we are proposing the replacement of [redacted] with the name "Pak" as a modifier of the Benzamycin tradename. Therefore, the proposed new tradename for our unit dose dual pouch erythromycin and benzoyl peroxide product is Benzamycin® Pak.

At this time, we are proposing no further changes to the labeling included in our original NDA.

Thank you for your attention. Please contact me at (610) 454-3027 if you have any questions.

Sincerely,

James P. Thompson

James P. Thompson
Regulatory Manager
Worldwide Regulatory Affairs

INITIAL

Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: October 24, 2000 Number of Pages (including cover sheet) - 3

TO: Alicia Cabrelli, Regulatory Analyst
COMPANY: Dermik Laboratories, Inc.
FAX #: 484-595-2785

MESSAGE: Minutes of our October 23, 2000, CMC Teleconference for NDA 50-769, Benzamycin Pak (erythromycin, 3% and benzoyl peroxide, 5% gel), are attached to this facsimile transmission.

Thank you.

FROM: Frank H. Cross, Jr., M.A., CDR
TITLE: Senior Regulatory Management Officer
PHONE #: 301-827-2063
FAX #: 301-827-2075/2091

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone.

APPEARS THIS WAY
ON ORIGINAL

Teleconference Date: October 23, 2000 Time: 1400 Location: N229

NDA 50-769, Benzamycin Pak (erythromycin, 3% and benzoyl peroxide, 5% gel)

Sponsor: Dermik Laboratories, Inc.

Purpose of Meeting: CMC Teleconference

Meeting Chair: Jim Vidra, Ph.D., Chemist, DNDCIII, HFD-830

Meeting Recorder (CSO/Project Manager): Frank H. Cross, Jr., M.A., CDR

FDA Attendees, titles and offices:

Jim Vidra, Ph.D., Chemist, DNDCIII, HFD-830
Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, DDDDP, HFD-540

Sponsor Attendees, titles and offices:

Wendy Chern, Ph.D., Manager, Dermatologic Product Development
Ed Smith, Manager, CMC Regulatory Affairs
Kimberly Forbes-McKean, Ph.D., Senior Director, Product Development and Commercialization
Jim Thompson, Manager, Regulatory Affairs
Alicia Cabrelli, Regulatory Analyst

The following conversation took place:

Agency:

Please submit the following:

1. A Reprocessing Statement or a brief summary of any proposed reprocessing procedures covering foreseeable deviations from specifications.

2. _____

3. _____

4. _____

5. The standard deviation for the 0.425 fill weight and where does the 10 pouch sampling originate from. Are 10 pouches selected from one lot or one batch, from one case, etc.?

Applicant:

The Applicant will submit the requested information in the next two or three days.

The teleconference ended amicably.

Signature, minutes preparer: /S/

Concurrence Chair (or designated signatory): /S/

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
. Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: November 20, 2000 Number of Pages (including cover sheet) - 20

TO: Alicia Cabrelli, Regulatory Analyst
COMPANY: Dermik Laboratories, Inc.
FAX #: 484-595-2785

MESSAGE: For your review/concurrence, please find attached to this facsimile transmission, draft labeling for NDA 50-769, Benzamycin Pak (erythromycin, 3% and benzoyl peroxide, 5%) Gel.

Thank you.

FROM: Frank H. Cross, Jr., M.A., CDR
TITLE: Senior Regulatory Management Officer
PHONE #: 301-827-2063
FAX #: 301-827-2075/2091

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21 Pages have been redacted in full from this document

Reason:

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__X__ b(4) CCI DRAFT LABELING
_____ b(4) TS
_____ b(5) Deliberative Process:
Attorney Client and Attorney Work Product Privilege
_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: November 21, 2000. Number of Pages (including cover sheet) - 2
TO: Alicia Cabrelli, Regulatory Analyst
COMPANY: Dermik Laboratories, Inc.
FAX #: 484-595-2785

MESSAGE: Re: NDA 50-769 Benzamycin Pak

Please find FDA's revised carton labeling.

FROM: Olga Cintron, R.Ph. for CDR Frank Cross
TITLE: Project Manager
PHONE #: 301-827-2020
FAX #: 301-827-2075/2091

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__X__ b(4) CCI DRAFT LABELING
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_____ b(5) Deliberative Process:
Attorney Client and Attorney Work Product Privilege
_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

New Drug Application No. 50-769
Item 8

Benzamycin
(erythromycin 3% and
benzoyl peroxide 5% gel)

8.10. Integrated Summary of Safety

This section contains a summary of the safety data for the clinical trials that were performed with the Benzamycin product (DL 6026).

APPEARS THIS WA
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: November 22, 2000. Number of Pages (including cover sheet) - 13
TO: Alicia Cabrelli, Regulatory Analyst
COMPANY: Dermik Laboratories
FAX #: 484-595-2785

MESSAGE:

Please find revised draft labeling for NDA 50-769, Benzamycin Pak.

FROM: Olga Cintron, R.Ph. for CDR Frank Cross
TITLE: Project Manager
PHONE #: 301-827-2020
FAX #: 301-827-2075/2091

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APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Division of Dermatologic and Dental Drug Products

Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard, HFD-540
Rockville, MD 20850

FACSIMILE TRANSMISSION

DATE: November 27, 2000 Number of Pages (including cover sheet) - 1

TO: Alicia Cabrelli, Regulatory Analyst
COMPANY: Dermik Laboratories, Inc.
FAX #: 484-595-2785

MESSAGE: Please commit to the following post marketing commitment for NDA 50-769, Benzamycin Pak (erythromycin, 3% - benzoyl peroxide, 5% topical gel).

Within 3 months of NDA Approval, conduct and report the results of a flammability or flashpoint study on the erythromycin gel since it contains ethyl alcohol.

Thank you.

FROM: Frank H. Cross, Jr., M.A., CDR
TITLE: Senior Regulatory Management Officer
PHONE #: 301-827-2063
FAX #: 301-827-2075/2091

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone.

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_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

HFD540/Cross

Meeting Date: September 15, 1998 Time: 1430 Location: N225
Meeting ID# 3147

Sponsor: Dermik Laboratories, Inc.

Purpose of Meeting: Pre-NDA Meeting

Meeting Chair: Jonathan K. Wilkin, M.D.

Meeting Recorder (CSO/Project Manager): Frank H. Cross, Jr., M.A., CDR

FDA Attendees, titles and offices:

Jonathan K. Wilkin, M.D., Division Director, DDDDP, HFD-540
Susan Walker, M.D., Dermatology Team Leader, DDDDP, HFD-540
Brenda Vaughan, M.D., Medical Officer, DDDDP, HFD-540
Wilson DeCamp. Ph.D., Chemistry Team Leader, DNDCIII, HFD-830
Paul Brown, Ph.D., Pharmacologist/Toxicologist, DDDDP, HFD-540
Dennis Bashaw, Ph.D., Biopharmaceutics Team Leader, DPEIII, HFD-880
R. Srinivasan, Ph.D., Biostatistics Team Leader, DOBIV, HFD-725
Valeria Freidlin, Ph.D., Biostatistician, DOBIV, HFD-725
Frank H. Cross, Jr., M.A., CDR, Senior Regulatory Management Officer, DDDDP, HFD-540

Sponsor Attendees, titles and offices:

Kimberly A. Forbes-McKean, Ph.D., Worldwide Director, Regulatory Affairs and Project Management, Dermik
Sharon Levy, M.D., Director of Clinical Research and Medical Affairs, Dermik
Ken Feld, Ph.D., Director, Product Development, Dermik
Steven Lerman, Ph.D., Senior Toxicologist, RPR
Dror Rom, Ph.D., Consulting Statistician
Jim Kulp, Manager, Clinical Research and Medical Affairs, Dermik
Jay Dorrell, Senior Research Scientist, Dermik
Linda Mahoney, Project Manager, Dermik
Donna Heren, Manager, Analytical Development, Dermik
Jim Thompson, Manager, Regulatory Affairs, RPR

With reference to the August 27, 1998, Meeting Briefing package, the Agency provided the following comments:

Chemistry, Manufacturing and Controls:

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Reason:

_____ b(2) 'low'
__x__ b(4) CCI MEETING MINUTES
__X__ b(4) TS
_____ b(5) Deliberative Process:
Attorney Client and Attorney Work Product Privilege
_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

f) The statement that there is no "measurable absorbance in the 300 to 700 nm range" (pg. 48) should be supported by complete spectra from 200 to 700 nm.

Pharmacology/Toxicology:

1. Responses to specific points for FDA input as listed by Sponsor:

a) The draft index appears to be acceptable.

b) The studies appear to be adequate to qualify degradants in the dual pouch formulation provided the concentrations of degradants in the dual pouch formulation under actual shelf-life conditions do not exceed those tested in the bridging study.

2. Additional comments:

As previously discussed, the Sponsor should include the results of the NDMA photococarcinogenicity study on benzoyl peroxide in the label if benzoyl peroxide is photococarcinogenic. If this study does not demonstrate that benzoyl peroxide is photococarcinogenic then the Sponsor should conduct an evaluation of the photococarcinogenic potential of the drug product.

Biopharmaceutics:

1. In vivo:

The Sponsor has conducted the in vivo study as requested comparing single pouch to multi-pouch application in the target (acne) population. The results of this study was that there was essentially no absorption using up to 3 pouches per day to affected skin.

2. In vitro:

a. The Sponsor has conducted in vitro cadaver skin penetration studies of the product comparing it to the marketed benzamycin gel. The studies suggest that there is no difference between the two products in term of dermal penetration. Given the extremely low bioavailability of the product (essentially <1%) we would agree with this conclusion.

b. The Sponsor has conducted additional in vitro studies analyzing mixing methods. Differences were seen when different mixing times were used, however, the Sponsor assigned these differences to non-homogenous mixing and does NOT intend to submit the results of these data with the NDA.

c. The Agency disagrees with the intention of the Sponsor to not submit the information contained in item 2 (above) and referred to on page 42 of the August 27, 1998, briefing package. Whether the data is supportive or not, the information should be submitted for our review. Reporting of only that data that an individual Sponsor considers supportive of their application is unacceptable.

d. Our review of the in vitro data in this manner, should not be construed by the Sponsor of Agency acceptance of this test as a "DPK"-like approach. The data will be used by the Agency to gain additional understanding of the effect of mixing times on absorption.

Clinical:

Specific topics submitted by the Sponsor for FDA input are as follows:

1. Labeling:

Dermik is requesting FDA input into the content and design of the labeling text on the dual pouch package and carton.

Labeling is a review issue which is addressed during the NDA review.

2. Clinical Data:

a) Format and Content of the Clinical Data Section:

i. Synopses, overall summaries of study results, and final study results should be grouped under separate headings for clinical pharmacology studies and clinical dermal safety studies (Section 8.5, pages 44-45).

ii. Efficacy variables should be defined in the overall study design.

b) Dermik is seeking FDA concurrence that it is acceptable to include the phototoxicity/photoallergy studies (#4476/04 and #4476/05) from previous Benzamycin Topical Gel NDA 50-557.

The above is acceptable based on the rationale provided by the Sponsor on pages 48 and 49 of the Briefing Package. Complete study reports including complete absorption spectra should be submitted.

c) Consumer Use Study:

Efficacy responses derived from questionnaires do not have regulatory utility.

d) Format of the Final Study Report for the Phase 3 Clinical Trials:

Acceptable. Please submit a copy of the final protocol(s) electronically. Microsoft WORD 6.0 format is acceptable.

e) Format of the Integrated Summary of Effectiveness Report:

In reference to Efficacy Variables (Briefing Package, pg 82), primary efficacy parameters were discussed and recommended at the End-of- Phase 2 Meeting(I.D.# 1790) with the Division on October 23, 1997. Primary efficacy parameters are as follows:

i. 1) reduction in lesion count and 2) the investigators global assessment. Baseline and Endpoint lesion counts, mean reduction, and mean percentage reduction from baseline should be presented for: non-inflammatory lesions, inflammatory lesions and total lesions.

ii. Superiority to vehicle in two of the three measures of lesion count reduction PLUS superiority to vehicle in the investigator's global assessment should be demonstrated.

iii. Levels of the investigator's global assessment should be clearly defined. Descriptions should be discrete for each level of global. Global assessments should be dichotomized to success/failure for efficacy evaluation.

f) Format of the Integrated Summary of Safety Report:

Acceptable.

Biostatistics:

1. According to page 85 of the Protocol: "The ITT population includes all patients with follow-up clinical evaluation." Does it mean any follow-up evaluation? The report should provide a clear definition of the ITT population.

a) In the minutes of the End-of-Phase 2 meeting (page 63), the following definition of the ITT population was recommended by the Division: "The ITT population includes all patients who were dispensed study treatment (active or vehicle)".

b) For the primary efficacy analysis in the superiority comparisons, the Division recommends to use the ITT population. For the primary efficacy analysis in the non-inferiority comparisons, the Division recommends to use the Efficacy Evaluable population (see ICH Guideline, Section E9).

2. In addition to Table 3 on page 87 , the study report should provide a list of patients excluded from the ITT and Efficacy Evaluable populations, by center, with the reasons for exclusions.

3. It is not clear why Tables 6 and 10 on pages 89 and 92 have rows both for Week 8 and ITT End. These rows should be the same because the primary efficacy timepoint for the ITT analysis should be Week 8 (The last available observation for a patient in the ITT population should be carried forward to Week 8).

4. SAS Datasets in version 6.12 should be provided at the time of the initial NDA submission on 3.5 inch media.

Note Added After Conclusion of Meeting as a Correction:

The specification o[redacted] for erythromycin (CMC Item #5) is the USP specification stated in the monograph "Erythromycin and Benzoyl Peroxide Topical Gel." Therefore, no justification for this specification is needed.

Signature, minutes preparer: /S/
Concurrence Chair (or designated signatory) /S/ 9/16/98
Attachment/Handouts:
Briefing Package, dated August 27, 1998, submitted to IND 12,193
General Format of "Review Notes" Section Handout

/ Pages have been redacted in full from this document

Reason:

_____ b(2) 'low'
__X__ b(4) CCI > MICRO LIMITS
__X__ b(4) TS
_____ b(5) Deliberative Process: Attorney Client and Attorney Work Product Privilege
_____ b(6) Personal Privacy
_____ b(7) Law Enforcement Records

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 50769/000**
Priority: **3S**
Org Code: **540**
Stamp: **27-JAN-2000** Regulatory Due: **27-NOV-2000**
Action Goal:
District Goal: **28-SEP-2000**
Applicant: **DERMIK LAB**
Brand Name: **BENZAMYCIN [redacted] ENOZYL PEROXIDE 5%**
Established Name:
Generic Name: **BENOZYL PEROXIDE 5%/ERYTHROMYCIN 3%**
Dosage Form: **GEL (GEL)**
Strength: **3% ERYTHROMYCIN, 5% BI**

FDA Contacts:			
F. CROSS JR	**(HFD-540)**	**301-827-2023**	**, Project Manager**
J. VIDRA	**(HFD-540)**	**301-827-2065**	**, Review Chemist**
W. DECAMP II	**(HFD-540)**	**301-827-2041**	**, Team Leader**

Overall Recommendation:

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CFN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **09-FEB-2000**
Responsibilities:

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CFN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **09-FEB-2000**
Responsibilities:

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **SUBMITTED TO OC**
Milestone Date: **09-FEB-2000**
Responsibilities:

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment: [redacted]

DMF No:
AADA No:

Profile: CFN OAI Status: NONE
Last Milestone: SUBMITTED TO OC
Milestone Date: 09-FEB-2000

Responsibilities:

Establishment: [redacted]

DMF No:
AADA No:

Profile: OIN OAI Status: NONE
Last Milestone: SUBMITTED TO OC
Milestone Date: 09-FEB-2000

Responsibilities:

Establishment: 2242829
WEST PHARMACEUTICAL SERVICE
1200 PACO WAY
LAKEWOOD, NJ 08701

DMF No:
AADA No:

Profile: OIN OAI Status: NONE
Last Milestone: SUBMITTED TO OC
Milestone Date: 09-FEB-2000

Responsibilities: FINISHED DOSAGE MANUFACTURER

TO BE I

Jim Kosloski N 186 3/00 ?
? Regina Brown (732) 940-8967, X-14
R
N. Brunswick District, Resident Bur. of M. FDA

• 2/11/00 - Regina will make dtrm. next Monday whether to inspect or not