

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20-743**

**CORRESPONDENCE**



NDA 20-743

OCT 10 1996

Dermik Laboratories, Inc.  
Attention: Ronald F. Panner  
500 Arcola Road  
Collegeville, PA 19426

Dear Mr. Panner:

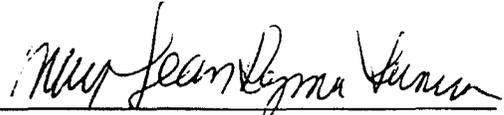
We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Noritate® (metronidazole cream) Cream, 1%  
Therapeutic classification: 3S  
Date of Application: September 30, 1996  
Date of Receipt: October 2, 1996  
Our Reference number: NDA 20-743

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit substantive review, this application will be filed under section 505(b) of the Act on December 1, 1996 in accordance with 21 CFR 314.101(a).

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

  
Mary Jean Kozma-Fornaro R.N., M.S.A  
Supervisory Project Manager  
Division of Dermatologic and Dental  
Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

cc:

Original NDA 20-743

HFD-540/DIV FILE

HFD-540/Cintron

DISTRICT OFFICE

HFD-540/OCintron/drafted 10-09-96

ACKNOWLEDGEMENT - AC

## FORWARD PLANNING MEETING MINUTES

**NDA 20-743**                      **Notritate (metronidazole cream) Cream, 1%**

**Date:** November 1, 1996  
**Sponsor:** Dermik Laboratories, Inc.  
**Pharmacologic class:** Synthetic nitroimidazole with antibacterial, antiprotozoal activity  
**Type:** 3S  
**Indication:** Topical treatment of rosacea including inflammatory papules, pustules and erythema  
**Active ingredient:** metronidazole  
**Filing Date:** 12/01/96  
**Regulatory Due Date:** March 30, 1997  
**User Fee Due Date:** October 1, 1997

**Attendees:**

HFD-540:  
L. Katz, M.D., Deputy Director  
M.J. Kozma-Fornaro, R.N., M.S.A., Acting Supv. Project Manager  
Syed Alam, Ph.D., Pharmacologist  
Jim Vidra, Ph. D., Chemist  
Wilson DeCamp, Ph.D., Team Leader/Chemistry  
R. Srinivasan, Ph.D., Team Leader/Biostatistics  
Shahla Farr, M.S., Biostatistics

HFD-880:  
Dennis Bashaw, Pharm.D., Biopharmaceutics

**Purpose:** To determine fileability of NDA 20-743.

**Outcome:** This new drug application was judged to be fileable.

<b>Expected date of draft review:</b>	Chemistry	May 1997
	Pharmacology	May 1997
	Biopharmaceutics	March 1997
	Biostatistics	May 1997
	Clinical	May 1997
	Microbiology	December 1996

**Plan:** The following requests will be conveyed to the sponsor:

### CLINICAL:

1. Line listings of Demographic data and Efficacy data should be provided.
2. All data listings in reference to the two U.S. pivotal trials DL6027-9510

and DL6027-9516 should be submitted.

3. An additional copy of Volume 25 should be provided which contains all the case record forms.
4. A presentation of world-wide knowledge based on both clinical trials and marketed products of the 1% cream and other topical and non-topical dosage forms would be needed.
5. For the repeated insult patch test DL6027-9611, details of subjects enrolled including data listings should be provided.
6. Listings of concomitant medications in all the dermal safety studies should be submitted.
7. Listings of drug exposure in the two U.S. pivotal trials are needed.
8. The Tables in Integrated Summary of Safety (Item 8H) give combined data from the two U.S. pivotal trials only. Since the Canadian studies were done with a very similar formulation, Tables combining all four Phase 3 studies ( two U.S. and two Canadian) should be presented.

#### BIOPHARMACEUTICS:

1. Due to the lack of in vivo plasma levels, an in vitro skin permeation study using cadaver skin and franz cells needs to be performed.

#### PHARMACOLOGY/TOXICOLOGY

1. The two new carcinogenicity studies in rat and mouse performed in house by Rhone-Poulenc should be officially submitted, as soon as possible. These carcinogenicity studies should include full reports along with the electronic format.
2. Labeling from the Canadian 1% cream product marketed in that country needs to be submitted.

The Labeling Day was estimated to be conducted by early June 1997.



---

Olga Cintron, R.Ph.  
Project Manager, HFD-540

Attachments (Checklists)

cc:

Original NDA 20-743  
HFD-540/DIV FILE  
HFD-540/DEP DIR/Katz  
HFD-540/CHEM/Vidra  
HFD-540/SR CHEM/DeCamp  
HFD-540/PHARM/Alam  
HFD-540/SR PHARM/Jacobs  
HFD-725/BIOSTAT/Farr  
HFD-725/SR BIOSTAT/Srinivasan  
HFD-540/MO/Ko  
HFD-880/SR BIOPHARM/Bashaw  
HFD-880/BIOPHARM/Kumi  
HFD-540/ACTING SUPV PROJ MGR/Kozma-Fornaro  
HFD-540/PROJ MGR/Cintron

file 11/13/96

MEMORANDUM OF TELEPHONE CONVERSATION

Date: December 13, 1996.

NDA: 20-743 Noritate Cream, 1%

External participants: Audrey Hackman, Dermik Laboratories, Inc.

FDA participants:

Janet Higgins, Chemist, HFD-540

Olga Cintron, Project Manager, HFD-540

*JH 12/13/96*  
*O.C. 12/13/96*

Discussion:

The following items were communicated to the sponsor regarding the Environmental Assessment of this application:

1. A MSDS for the active ingredient cannot be confidential. Please revise the FOIable Environmental Assessment to include a non-confidential MSDS for metronidazole.
2. Both the confidential and FOIable Environmental Assessments should be signed.

The sponsor agreed to provide these items. The conversation ended amicably.

cc:

Original NDA 20-743

HFD-540/DIV FILE

HFD-540/DeCamp

HFD-540/Higgins

HFD-540/Kozma-Fornaro

MEMORANDUM OF TELEPHONE CONVERSATION

Date: November 6, 1996

NDA: 20-743

Drug: Noritate Cream, 1%

Sponsor: Dermik Laboratories, Inc.

External participants: Audrey Hackman, Regulatory Affairs Associate, Dermik Labs.  
Gary Feiss, Senior Project Manager, Dermik Labs.  
Kim Forbes-Mckean, Dir. Regulatory Affairs/Proj. Mgt., Dermik Labs.  
Michael Pino, Staff Pathologist, Dermik Labs.  
Cynthia Russo, Senior Clinical Research Associate, Dermik Labs.  
Raymond Tobey, M.D., V.P. Research and Development, Dermik Labs.

FDA participants: R. Srinivasan, Ph.D., Biostatistics, HFD-725  
Shahla Farr, M.S., Biostatistics, HFD-725  
Steven Thomson, Ph.D., Biostatistics, HFD-725  
Olga Cintron, R.Ph., Project Manager, HFD-540

*Olga Cintron*  
11/6/96

Subject: Carcinogenicity studies data analysis

Discussion: After a brief introduction of each participant, the sponsor proceeded to clarify that the two summaries of carcinogenicity studies provided in the NDA were conducted in the late 70's. Also, that it was discussed at the Pre NDA meeting that no more pharm/tox studies were required, since they were seeking class labeling for topical metronidazole. Therefore, it was not necessary to conduct carcinogenicity studies.

The Agency proceeded to ask if it was possible to provide the full text of the studies including full reports and tables, and if there was not much statistical analysis, the possibility of converting the tables from those full reports into an electronic format.

The sponsor agreed to submit the full reports including the tables. However, the possibility of converting parts of the tables of full reports into electronic format will have to be evaluated.

Actions: The sponsor will formally submit full reports including tables for the two carcinogenicity studies.

The Agency will contact the sponsor for further requests as necessary with respect to this issue.

cc:

Original NDA 20-743

HFD-540/ DIV FILE

HFD-540/Pharm/Alam

HFD-540/TL Pharm/Jacobs

HFD-725/TL Biostat/Srinivasan

HFD-725/Biostat/Farr

HFD-725/Biostat/Thomson

HFD-540Act. Supv. Proj. Mgt./Kozma-Fornaro

BL  
ORIG AMENDMENT



DERMIK LABORATORIES, INC.

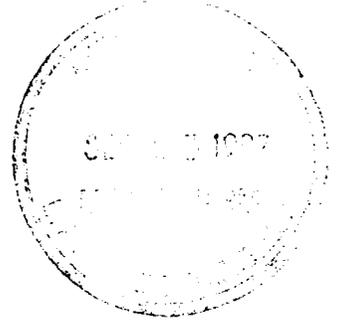
Dedicated to Dermatology™

A RHÔNE-POULENC RORER COMPANY

PLICATE

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

September 2, 1997



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

NDA #20-743  
Noritate® (metronidazole cream)  
Cream, 1%

Response to FDA Request for  
Information

Dear Dr. Wilkin,

Reference is made to the proposed labeling for Noritate® Cream that was faxed to us by Supervising Project Manager, Mary Jean Kozma-Fornaro, on August 28, 1997. This is to reiterate that we accept the package insert labeling.

As discussed with Ms. Kozma-Fornaro, we are proposing one minor change on the carton to be consistent with the package insert. In the list of ingredients, the word "and" was inserted before propylparaben. A copy of the carton is attached.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Senior Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

Desk Copy: Ms. Mary Jean Kozman-Fornaro

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

July 1, 1997

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

BZ  
NDA ORIG AMENDMENT



NDA #20-743  
Noritate® (metronidazole cream)  
Cream, 1%

Response to FDA Request for Information  
- Revised Proposed Draft Labeling

Dear Dr. Wilkin,

Reference is made to two faxes dated May 20 and June 14, 1997, from Ms. Olga Cintron which contained revisions to the proposed package insert requested by the pharmacology and clinical reviewers, respectively, for Noritate® (metronidazole cream) Cream, 1%. Reference is also made to your June 20, 1997 letter containing additional requests from the chemistry reviewer.

Please find attached a revised proposed package insert which responds the the labeling comments from the pharmacology, clinical, and chemistry reviewers.

We believe that this submission fully responds to all outstanding comments regarding the proposed package insert. If you have any questions regarding this submission, please contact me at (610) 454-3026.

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> (N/A)
CSO INITIALS	DATE

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

ORIGINAL



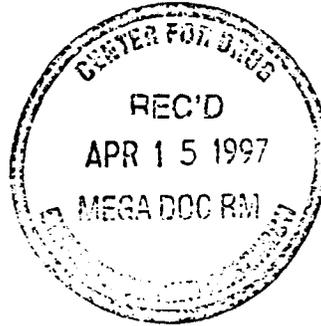
DERMIK LABORATORIES, INC.

A RHÔNE-POULENC RORER COMPANY

Dedicated to Dermatology™

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

April 14, 1997



BL  
ORIG AMENDMENT

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

**NDA #20-743**  
**Noritrate (metronidazole 1% cream)**

**Response to FDA Comments on Labeling**  
**- Pharmacology / Toxicology**  
**- Revised Draft Labeling**

Dear Dr. Wilkin,

Reference is made to the February 26, 1997 fax from Ms. Olga Cintron, Project Manager, which contained recommendations and comments on the draft labeling from the reviewing pharmacologist.

Please find enclosed Dermik's responses to the pharmacologist's comments. Also enclosed is a revised draft package insert which incorporates the wording proposed by Dermik to respond to the pharmacologist's comments.

We believe that this submission fully responds to the pharmacologist's requests. If you have any questions regarding this submission, please contact me at (610) 454-3026.

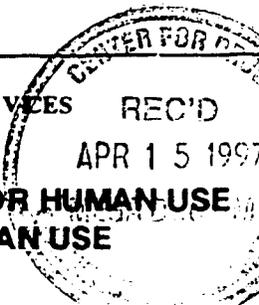
Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

REVIEWS COMPLETED	
USO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

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



Form Approved: OMB No. 0910-0001  
Expiration Date: December 31, 1995.  
See OMB Statement on Page 3.

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

(Title 21, Code of Federal Regulations, 314)

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT Dermik Laboratories, Inc.	DATE OF SUBMISSION April 14, 1997
ADDRESS (Number, Street, City, State and ZIP Code) 500 Arcola Road Collegetown, PA 19426	TELEPHONE NO. (Include Area Code) (610) 454-3026
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued) 20-743

DRUG PRODUCT

ESTABLISHED NAME (e.g., USP/USAN) metronidazole	PROPRIETARY NAME (If any) Noritate®
--	--

CODE NAME (If any) n/a	CHEMICAL NAME 2-methyl-5-nitroimidazole-1-ethanol
---------------------------	--

DOSAGE FORM Cream	ROUTE OF ADMINISTRATION topical	STRENGTH(S) 1%
----------------------	------------------------------------	-------------------

POS INDICATIONS FOR USE

Topical treatment of rosacea including inflammatory papules, pustules and erythema

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:

DMF  
DMF  
DMF  
DMF

INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)

THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)       THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION
--------------	--------------------------------

TYPE SUBMISSION (Check one)

PRESUBMISSION       AN AMENDMENT TO A PENDING APPLICATION       SUPPLEMENTAL APPLICATION  
 ORIGINAL APPLICATION       RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)       APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)



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

January 31, 1997

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

**NDA #20-743**  
**Noritate® (metronidazole 1% cream)**

**Response to FDA Request for  
Information**  
**- Human Pharmacokinetic and  
Bioavailability Information**

**Revised Proposed Package Insert**

Dear Dr. Wilkin,

Reference is made to the November 5, 1996 fax from Ms. Olga Cintron, Project Manager, which contained a request from the biopharmaceutics reviewer.

Therefore, please find enclosed Dermik's response to the request from the biopharmaceutics reviewer. We believe that this information is relevant to the proposed labeling for this product and have made a single change to the draft package insert. Copies of the revised proposed package insert highlighting the change are also included in this submission.

We believe that this submission fully responds to the above-mentioned request. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures



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

Form Approved: OMB No. 0910-0001.  
Expiration Date: December 31, 1995.  
See OMB Statement on Page 3.

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

(Title 21, Code of Federal Regulations, 314)

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT Dermik Laboratories, Inc.	DATE OF SUBMISSION January 31, 1997
ADDRESS (Number, Street, City, State and ZIP Code) 500 Arcola Road Collegetown, PA 19426	TELEPHONE NO. (Include Area Code) (610) 454-3026
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued) 20-743

DRUG PRODUCT

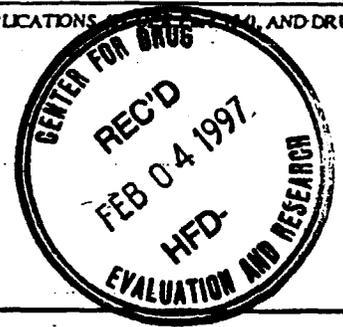
ESTABLISHED NAME (e.g., USP/USAN) metronidazole	PROPRIETARY NAME (If any) Noritate <sup>®</sup>
CODE NAME (If any) n/a	CHEMICAL NAME 2-methyl-5-nitroimidazole-1-ethanol
DOSAGE FORM cream	ROUTE OF ADMINISTRATION topical
	STRENGTH(S) 1%

PROPOSED INDICATIONS FOR USE

Topical treatment of rosacea including inflammatory papules, pustules, and erythema

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314.10), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:

IND  
DMF  
DMF  
DMF



INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)

THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)       THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION
--------------	--------------------------------

TYPE SUBMISSION (Check one)

PREVIOUS SUBMISSION       AN AMENDMENT TO A PENDING APPLICATION       SUPPLEMENTAL APPLICATION  
 ORIGINAL APPLICATION       RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)       APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)



**DERMIK LABORATORIES, INC.**

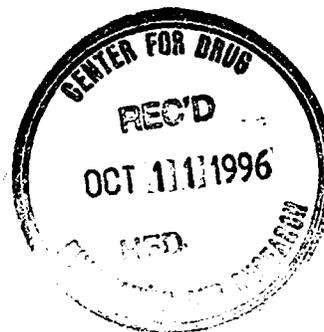
A RHÔNE-POULENC RORER COMPANY

*Dedicated to Dermatology™*

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

September 30, 1996

Jonathan K. Wilkin, M.D., Director  
Division of Dermatologic and Dental  
Drug Products  
Attention: Document Control Room  
Food and Drug Administration  
Park Building, Room 214  
12420 Parklawn Drive  
Rockville, MD 20852



**NDA 20-743**  
**Noritrate®**  
**(metronidazole 1% cream)**

**ORIGINAL NEW DRUG  
APPLICATION**

Dear Dr. Wilkin:

In accordance with 21 CFR 314.50 of the Federal Food, Drug and Cosmetic Act, Dermik Laboratories, Inc. is submitting an Original New Drug Application for Noritrate® (metronidazole 1% cream) which demonstrates the efficacy and safety of the product in the topical treatment of patients with rosacea including inflammatory papules, pustules, and erythema.

This application contains the following sections: 1) Index, 2) Overall Summary, 3) Chemistry, Manufacturing and Controls, 4) Methods Validation Package and Labeling, 5) Nonclinical Pharmacology and Toxicology, 6) Human Pharmacokinetics and Bioavailability, 7) Microbiology, 8) Clinical data, 10) Statistical, 11) Case Report Tabulations, 12) Case Report Forms, 13) and 14) Patent information.

Case report form tabulations for the individual medical reports are included in the appendices of each report when available and are located in the Clinical Data and Statistical sections of this application.

Jonathan K. Wilkin, M.D.  
Page 2 of 2  
September 30, 1996  
NDA 20-743

In accordance with the Prescription Drug User Fee Act of 1992, a check (Check No. 822249), in the amount of \_\_\_\_\_ was sent to the Food and Drug Administration, Philadelphia, Pennsylvania on September 24, 1996. The application was assigned the User Fee Identification Number 3080.

As required by Section 306(k)(1) of the Generic Drug Enforcement Act [21 U.S.C. 335a (k)(1)], we hereby certify that, in connection with this application, Dermik Laboratories, Inc. did not and will not use in any capacity the services of any person debarred under subsections 3-6(a) or (b) of the act.

Dermik Laboratories, Inc. considers the information in this application to be confidential and proprietary and we request that no portions thereof be disclosed to third parties, under FOI or otherwise, without first obtaining written consent from Dermik Laboratories, Inc.

If you have any questions or require any additional information during review of this application, please contact me at (610) 454-3026.

Sincerely yours,

James P. Thompson / for

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures





**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

September 26, 1997

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

**NDA #20-743**  
**Noritrate® (metronidazole cream)**  
**Cream, 1%**

**Response to FDA Request for Information**  
**- Microbiology**  
**- Chemistry, Manufacturing, and Controls**

Dear Dr. Wilkin,

Reference is made to the September 25, 1997 fax from Ms. Mary Jean Kozma-Fornaro requesting that Dermik restate the Phase IV commitment requested by the microbiology reviewer.

Therefore, as requested, the Phase IV microbiology commitment follows.

The results of this testing will be submitted in the NDA annual report.

We believe that this submission fully responds to all outstanding comments regarding this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs



**DERMIK LABORATORIES, INC.**

*Dedicated to Dermatology™*

A RHÔNE-POULENC RORER COMPANY

PLICATE

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

September 2, 1997



**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

**NDA #20-743**  
**Noritate® (metronidazole cream)**  
**Cream, 1%**

**Response to FDA Request for  
Information**

Dear Dr. Wilkin,

Reference is made to the proposed labeling for Noritate® Cream that was faxed to us by Supervising Project Manager, Mary Jean Kozma-Fornaro, on August 28, 1997. This is to reiterate that we accept the package insert labeling.

As discussed with Ms. Kozma-Fornaro, we are proposing one minor change on the carton to be consistent with the package insert. In the list of ingredients, the word \_\_\_\_\_ was inserted before propylparaben. A copy of the carton is attached.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Senior Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

Desk Copy: Ms. Mary Jean Kozman-Fornaro

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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

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

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

FOR FDA USE ONLY

APPLICATION NUMBER

NDA 20-743

**APPLICANT INFORMATION**

NAME OF APPLICANT

Dermik Laboratories, Inc.

DATE OF SUBMISSION

September 2, 1997

TELEPHONE NO. (Include Area Code)

(610) 454-3026

FACSIMILE (FAX) Number (Include Area Code)

(610) 454-5287

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

500 Arcola Road  
Collegeville, PA 19426

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

**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)

metronidazole

PROPRIETARY NAME (trade name) IF ANY

Noritate

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any)

2-methyl-5-nitroimidazole-1-ethanol

CODE NAME (if any)

n/a

DOSAGE FORM:

cream

STRENGTHS:

1%

ROUTE OF ADMINISTRATION:

topical

(PROPOSED) INDICATION(S) FOR USE: Topical treatment of rosacea including inflammatory papules, pustules and erythema

**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

Response to FDA Request for Information

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 (CFR), 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.

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

DMF

DMF

DMF

DMF

DUPLICATE



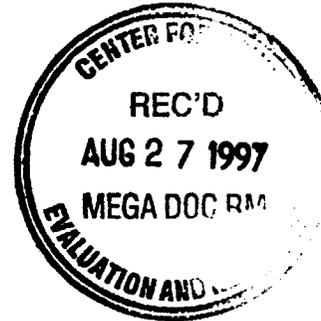
DERMIK LABORATORIES, INC.

Dedicated to Dermatology™

A RHÔNE-POULENC RORER COMPANY

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

August 26, 1997



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

**NDA #20-743**  
**Noritate®(metronidazole cream)**  
**Cream, 1%**

**Response to FDA Request for Information**  
**- Chemistry, Manufacturing, and Controls**  
**- Microbiology**

Dear Dr. Wilkin,

Reference is made to the August 21, 1997 fax from Ms. Olga Cintron, Project Manager which contained a request from the chemistry reviewer for a post-approval commitment to evaluate globule size. Reference is also made to the August 22, 1997 telephone conversation with Ms. Cintron and Dr. Janet Higgins, Reviewing Chemist, and the August 26, 1996 telephone conversation with Dr. Peter Cooney, Microbiology Supervisor regarding expiration dating.

As requested by Dr. Higgins, Dermik commits to develop and validate a method to evaluate globule size. The first five stability batches packaged in 30 g tubes will be tested for globule size both at release and as a part of stability testing. The results of these measurements will be submitted in the next NDA annual report, and, if appropriate, a supplemental application will be submitted to propose a regulatory specification and method. ✓

Please note that stability batches will be selected based upon the revised stability commitment submitted on July 21, 1997 which states that,

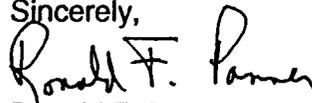
Regarding expiration dating, Dermik submitted a report containing additional stability data up to 12 months at room temperature on June 20, 1997. Based upon that data, as well as the supportive stability data provided in the original NDA, Dermik proposed a twenty-four (24) month expiration date under room temperature storage. Dermik will continue to conduct microbiological testing under room temperature storage conditions as indicated in ✓

Jonathan K. Wilkin, M.D., Director  
August 26, 1996  
Page 2

the stability protocol submitted in the original NDA and in the revised stability commitment submitted on July 21, 1997. The results of this testing will be submitted in the NDA annual report.

We believe that this submission fully responds to all outstanding comments regarding this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,



Ronald F. Panner  
Senior Director  
Worldwide Regulatory Affairs

RFP/alh/arz  
Enclosures

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

NDA 20-743

APPLICANT INFORMATION

NAME OF APPLICANT  
Dermik Laboratories, Inc.

DATE OF SUBMISSION  
August 26, 1997

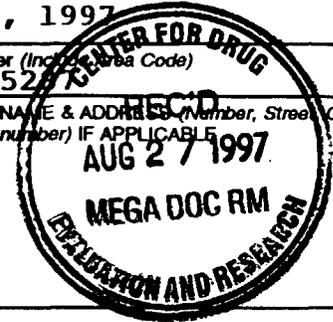
TELEPHONE NO. (Include Area Code)  
(610) 454-3026

FACSIMILE (FAX) Number (Include Area Code)  
(610) 454-5276

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

500 Arcola Road  
Collegeville, PA 19426

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



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)  
metronidazole

PROPRIETARY NAME (trade name) IF ANY  
Noritate

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (if any)  
2-methyl-5-nitroimidazole-1-ethanol

CODE NAME (if any)  
n/a

DOSAGE FORM:  
cream

STRENGTHS:  
1%

ROUTE OF ADMINISTRATION:  
topical

(PROPOSED) INDICATION(S) FOR USE:

Topical treatment of rosacea including inflammatory papules, pustules and

INDICATION 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

Response to FDA Request for Information - CMC & Microbiology

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 the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

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

DMF  
DMF  
DMF  
DMF



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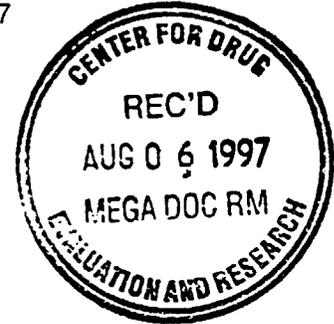
A RHÔNE-POULENC RORER COMPANY

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

CARD FILE

August 5, 1997

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



**NDA #20-743**  
**Noritate® (metronidazole cream)**  
**Cream, 1%**

**Response to FDA Request for Information**  
- **Chemistry, Manufacturing, and Controls**  
- **Methods Validation**  
- **Revised Draft Labeling (tube and carton labels)**

Dear Dr. Wilkin,

Reference is made to the July 31 and August 1, 1997 telephone conversations with Dr. Wilson DeCamp, Dr. Janet Higgins, and Ms. Olga Cintron in which the Agency requested that Dermik clarify certain information included in our July 21, 1997 submission.

Therefore, please find enclosed clarifications of the chemistry, manufacturing, and controls information and methods validation information included in our July 21, 1997 submission. In addition, revised mock-up copies of the tube and carton labels incorporating the changes requested by the Agency are included in this submission.

We believe that this submission fully responds to all outstanding comments regarding this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/arz



DERMIK LABORATORIES, INC.

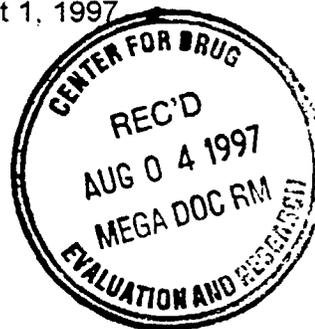
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P.O. BOX 1200  
COLLEGEVILLE, PA 19426-0107  
TEL. 610-454-8000

August 1, 1997

Olga Cintron, R.Ph., Project Manager  
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 N248  
Rockville, MD 20850



NDA #20-743  
Noritate® (metronidazole cream)  
Cream, 1%

Electronic Stability Data Sets

Dear Ms. Cintron,

Reference is made to the your July 30, 1997 fax containing the details of a request from Dr. R. Srinivasan and Dr. Shala Farr that the data sets used for the 24-month stability regression analysis be submitted on diskette.

Please find enclosed a diskette containing the electronic data sets in SAS, as well as the complete data listings. No computer viruses were detected when this diskette was scanned using the F-PROT Professional Anti-virus Program (version 2.26).

If you have any questions regarding this submission, please contact me at (610) 454-5139.

Sincerely,

Audrey L. Hackman  
Senior Regulatory Affairs Associate  
Worldwide Regulatory Affairs

ALH/maf  
Enclosures

DUPLICATE



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BM  
ORIG AMENDMENT

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

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



NDA #20-743  
Noritate®(metronidazole cream)  
Cream, 1%

Response to FDA Request for Information  
- Clinical

Dear Dr. Wilkin,

Reference is made to the July 23, 1997 telephone conversation with Ms. Olga Cintron in which she requested that Dermik clarify certain information included in Dermik's June 13, 1997 response to FDA's request for clinical information. A clarification of that information is presented below.

Attachment B in the June 13, 1997 submission was a copy of the section of the application form from the Canadian New Drug Submission (NDS) which details the quantitative composition of the formulation. This quantitative statement listed the amount of Purified Filtered Water, USP to be 0.81 mg per gram of product. However, the correct amount of Purified Filtered Water, USP is 0.81 mL or 810 mg per gram of product. The discrepancy was confirmed to be due to a transcription error on the NDS application form.

We believe that this submission fully responds to all outstanding comments regarding this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/arz

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

Form Approved: OMB No. 0910-0001.  
Expiration Date: December 31, 1995.  
See OMB Statement on Page 3.

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

(Title 21, Code of Federal Regulations, 314) **FOR FD**

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDV/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT  
Dermik Laboratories, Inc.

DATE OF SUBMISSION  
July 28, 1997  
TELEPHONE NO. (Include Area Code)  
(610) 454-3026

ADDRESS (Number, Street, City, State and ZIP Code)  
500 Arcola Road  
Collegeville, PA 19426

NEW DRUG OR ANTIBIOTIC APPLICATION  
NUMBER (if previously issued)  
20-743

DRUG PRODUCT

ESTABLISHED NAME (e.g., USP/USAN)  
metronidazole

PROPRIETARY NAME (if any)  
Noritate®

CODE NAME (if any)  
n/a

CHEMICAL NAME  
2-methyl-5-nitroimidazole-1-ethanol

DOSAGE FORM  
cream

ROUTE OF ADMINISTRATION  
topical

STRENGTH(S)  
1%

PROPOSED INDICATIONS FOR USE

Topical treatment of rosacea including inflammatory papules, pustules and erythema.

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:

DMF  
DMF  
DMF  
DMF

INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)

THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)  THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG

HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION (Check one)

PRELIMINARY SUBMISSION  AN AMENDMENT TO A PENDING APPLICATION  SUPPLEMENTAL APPLICATION  
 ORIGINAL APPLICATION  RESUBMISSION

SPECIFIC REGULATIONS TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)  APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)



DERMIK LABORATORIES, INC.

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A RHÔNE-POULENC RORER COMPANY

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

July 21, 1997



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

**NDA #20-743**  
**Noritate® (metronidazole cream)**  
**Cream, 1%**

**Response to FDA Request for Information**  
**- Chemistry, Manufacturing, and Controls**  
**- Methods Validation Package**

Dear Dr. Wilkin,

Reference is made to your letter dated June 20, 1997 in which you requested certain information in order to complete your review of the chemistry section of the above-mentioned NDA.

Please find enclosed the additional chemistry and methods validation information requested in your June 20th letter.

We believe that this submission fully responds to all outstanding comments regarding this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

ORIGINAL



DERMIK LABORATORIES, INC.

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

July 1, 1997

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

BZ  
NDA ORIG AMENDMENT



NDA #20-743  
Noritate® (metronidazole cream)  
Cream, 1%

Response to FDA Request for Information  
- Revised Proposed Draft Labeling

Dear Dr. Wilkin,

Reference is made to two faxes dated May 20 and June 14, 1997, from Ms. Olga Cintron which contained revisions to the proposed package insert requested by the pharmacology and clinical reviewers, respectively, for Noritate® (metronidazole cream) Cream, 1%. Reference is also made to your June 20, 1997 letter containing additional requests from the chemistry reviewer.

Please find attached a revised proposed package insert which responds the the labeling comments from the pharmacology, clinical, and chemistry reviewers.

We believe that this submission fully responds to all outstanding comments regarding the proposed package insert. If you have any questions regarding this submission, please contact me at (610) 454-3026.

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/ah/maf  
Enclosures



DERMIK LABORATORIES, INC.

A RHÔNE-POULENC RORER COMPANY

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

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

June 20, 1997



BC  
NDA ORIG AMENDMENT

NDA #20-743

Noritate® (metronidazole 1% cream)

Response to FDA Request for Information  
- Chemistry, Manufacturing and Controls

Dear Dr. Wilkin,

Reference is made to the May 22, 1997 telephone conversation in which Ms. Olga Cintron, Project Manager, requested, on behalf of the reviewing chemist, that Dermik submit a UV spectrum for the drug product. Reference is also made to a subsequent June 3, 1997 telephone conversation in which Ms. Olga Cintron agreed that Dermik should also submit additional updated chemistry information.

As requested by Ms. Cintron, please find enclosed the following information which updates the chemistry, manufacturing, and controls section of this NDA:

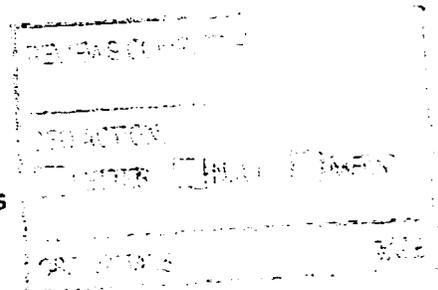
1. Report of the UV-VIS Absorbance Spectrum Scan for Noritate
2. Revised Manufacturing Master Document
3. Revised Test Method for Determination of Particle Size of Metronidazole
4. 12-month Stability Report

In addition, a summary of the changes contained in this submission is attached.

Dermik believes that this submission fully responds to the reviewing chemist's request. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs



RFP/alh/maf  
Enclosures



ORIGINAL



DERMIK LABORATORIES, INC.

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COLLEGEVILLE, PA 19426-0107  
TEL. 610-454-8000

June 11, 1997

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



RI

REVISION AMENDMENT

**NDA #20-743**  
**Noritate (metronidazole 1% cream)**

**Response to FDA Request for  
Information**

- Microbiology
- Chemistry, Manufacturing and Controls

Dear Dr. Wilkin,

Reference is made to a series of telephone conversations between the reviewing microbiologist, Neal Sweeney, and Kenneth Feld, Ph.D., Director, Dermik Product Development regarding Dermik's February 4, 1997 submission. As discussed with Mr. Sweeney, Dermik agrees to revise the microbial specifications for Noritate.

Therefore, please find attached the revised specifications for the drug product. Blank certificates of analysis reflecting this revision for the 30 g and 3.5 g tubes and an updated copy of the microbiology Test Method M025 are also enclosed. Because the microbiology section of this NDA has been extracted from the chemistry, manufacturing, and controls section, this submission updates both sections of the NDA.

We believe that this submission fully responds to the microbiologist's request. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

*Ronald F. Panner*  
Ronald F. Panner

Group Director  
Worldwide Regulatory Affairs

RFP/alh/arz  
Enclosures

REVIEWS COMPLETED
DISPOSITION
<input type="checkbox"/> RETURN <input type="checkbox"/> REVAL <input type="checkbox"/> MEMO

ORIGINAL



DERMIK LABORATORIES, INC.

A RHÔNE-POULENC RORER COMPANY

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

April 9, 1997

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

BPA  
NDA SUPP AMENDMENT

NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for Information  
- Clinical

Dear Dr. Wilkin,

Reference is made to the November 5, 1996 fax from Ms. Olga Cintron, Project Manager, which contained several requests from the Medical Officer and to the subsequent November 18, 1996 fax further clarifying one of those requests. Reference is also made to the December 2 and 13, 1996 and February 5, 1997 submissions containing Dermik's responses to those requests.

Please find enclosed Dermik's response to the Medical Officer's request for a presentation of the worldwide knowledge of the safety of metronidazole. No new safety issues associated with the use of topically applied metronidazole are suggested by these data.

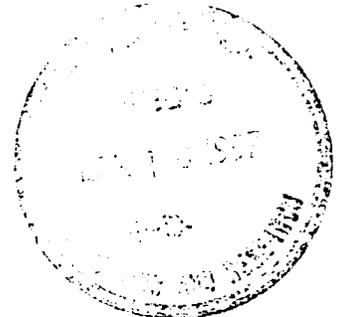
We believe that this submission fully responds to the Medical Officer's requests. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

RECEIVED	
DATE	
BY	
INITIALS	
REMARKS	



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

February 4, 1997



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

BI  
NDA ORIG AMENDMENT

NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for  
Information  
- Microbiology

Dear Dr. Wilkin,

Reference is made to the January 15, 1997 fax from Ms. Olga Cintron, Project Manager, which contained a request from the microbiology reviewer.

Therefore, please find enclosed Dermik's response to the request from the microbiology reviewer. We believe that this submission fully responds to this request. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/maf  
Enclosures

REVIEWS COMPLETED  
CSC ACTION  
 LETTER  MAIL  OTHER  
CSC INITIALS

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

February 5, 1997

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

BM  
NDA ORIG AMENDMENT

NDA #20-743  
Noritate®(metronidazole 1% cream)

Response to FDA Request for Information  
- Clinical

Dear Dr. Wilkin,

Reference is made to the November 5, 1996 fax from Ms. Olga Cintron, Project Manager, which contained several requests from the Medical Officer. Reference is also made to the December 2, 1996 submission containing Dermik's responses to those requests.

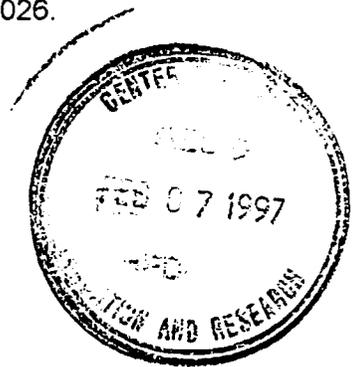
Please find enclosed the tabulations requested by the Medical Officer which integrate the adverse event data from the two pivotal US Phase III studies with the adverse event data from the two supportive Canadian Phase III studies. A summary of the FDA's requests and Dermik's responses are included in this submission. As indicated in our December 2, 1996 submission, integration of the Canadian data required additional preparation time because electronic data files were not available.

We believe that this submission fully responds to above-mentioned request. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

*Ronald F. Panner*

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs



RFP/alh/maf  
Enclosures

SEARCHED  
SERIALIZED  
 LETTER  MAIL  INDEXED  
FEB 07 1997  
FBI - ROCKVILLE

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

December 20, 1996

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

BS  
NDA 20-743

NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for  
Information  
- Statistical Information

Dear Dr. Wilkin,

Reference is made to the December 18, 1996 telephone conversation between Dermik's Ms. Audrey Hackman and Ms. Olga Cintron, Project Manager, in which Ms. Cintron indicated that Dr. Shala Farr, Biostatistician, had additional questions regarding the SAS data sets included in our November 22, 1996 submission.

Included in this submission are the electronic and paper copies of the SAS data sets for patient treatment allocation which should facilitate Dr. Farr's review. No computer viruses were detected when this diskette was scanned using the F-PROT Professional Anti-virus Program (version 2.24B). The disk is enclosed in the Statistical Reviewer's copy of the submission.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

PROGRAMS COMPLETED  
ACTION  
DATE  
BY



ORIGINAL



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TEL. 610-454-8000

December 19, 1996

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

BC

NDA ORIGINAL SUBMITTAL



**NDA #20-743**  
**Noritrate®(metronidazole 1% cream)**

**Response to FDA Request for  
Information**  
**- Chemistry, Manufacturing and Controls**

Dear Dr. Wilkin,

Reference is made the December 13, 1996 telephone request from Dr. Janet Higgins, Reviewing Chemist, and Ms. Olga Cintron, Project Manager, that Dermik revise and resubmit both the confidential and nonconfidential versions of the Environmental Assessment.

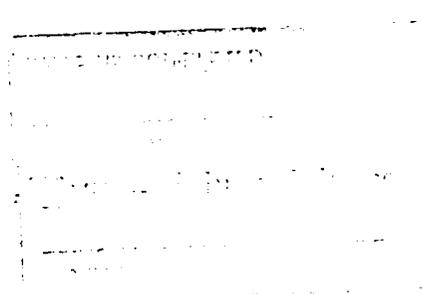
Therefore, please find enclosed the revised confidential and nonconfidential versions of the Environmental Assessment as requested by Dr. Higgins which supercede the previously submitted versions of the Environmental Assessment.

This submission fully responds to the request for information to support the chemistry review of this NDA. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures



DUPLICATE

ORIG AMENDMENT

Bm



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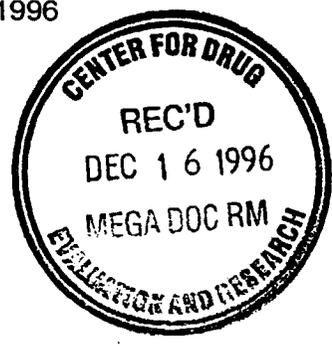
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December 13, 1996

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



NDA #20-743  
Noritate®(metronidazole 1% cream)

Response to FDA Request for  
Information  
- Clinical

Dear Dr. Wilkin,

Reference is made the December 10, 1996 telephone conversation between Ms. Olga Cintron and Ms. Audrey Hackman in which Ms. Cintron indicated that Dr. Ko, Medical Officer, requested that additional information be submitted.

This submission contains responses to Dr. Ko's requests. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

*Audrey L. Hackman* /fow

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

ORIGINAL  
NEW CORRESP  
NC



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TEL. 610-454-8000

December 2, 1996

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



NDA #20-743  
Noritate®(metronidazole 1% cream)

Response to FDA Request for  
Information  
- Clinical

Dear Dr. Wilkin,

Reference is made the November 5, 1996 fax from Ms. Olga Cintron which requested that certain clinical, biopharmaceutics, and pharmacology / toxicology information be submitted.

This submission contains responses to the clinical requests posed in that fax. A summary of FDA Requests and Dermik Responses is enclosed. As noted within, certain safety information requested will be provided in an additional submission.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

ORIGINAL



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COLLEGEVILLE, PA 19426-0107  
TEL. 610-454-8000

November 22, 1996



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

BS  
NDA ORIG AMENDMENT

NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for  
Information

Dear Dr. Wilkin,

Reference is made to the October 29, 1996 telephone conversation between Dermik's Ms. Audrey Hackman and FDA's Dr. Shala Farr, Biostatistician, during which Dr. Farr requested that safety and efficacy line listings be submitted to the NDA. Reference is also made to a subsequent fax from Ms. Olga Cintron, FDA Project Manager, confirming the details of Dr. Farr's request.

Included in this submission are the electronic and paper copies of the information requested by Dr. Farr.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

REVIEWS COMPLETED
CSO ACTION:
<input type="checkbox"/> LETTER <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS
DATE

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TEL. 610-454-8000

November 14, 1996

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



BC  
ORIGINAL AMENDMENT

NDA #20-743  
Noritate® (metronidazole 1%-cream)

Response to FDA Request for  
Information  
- Chemistry, Manufacturing and Controls

Dear Dr. Wilkin,

Reference is made the November 8, 1996 telephone conversation between Ms. Olga Cintron, Project Manager, and Ms. Audrey Hackman in which Ms. Cintron requested that the confidential sections of the Environmental Assessment be identified.

In accordance with CDER's November 1995 Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements, Dermik has identified and removed any confidential information included in the original Environmental Assessment.

Therefore, as requested, included in this submission is a non-confidential version of the Environmental Assessment. This version should be appended to the Environmental Assessment included in the original NDA submitted on September 30, 1996.

This submission fully responds to the request for information to support the chemistry review of this NDA. Information responding to other requests will be submitted under separate cover. If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director

Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

REVIEWS COMPLETED
CSO ACTION:
<input type="checkbox"/> LETTER <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEND
CSO INITIALS
DATE

**ORIGINAL**  
**NEW CORRESP**

*NC*

**DERMIK LABORATORIES, INC.**

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

November 14, 1996

*noted*  
*11/21/96*  
*1032*

Olga Cintron, Project Manager  
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 N248  
Rockville, MD 20850



NDA #20-743  
Noritate® (metronidazole 1% cream)

Review Copy

Dear Ms. Cintron,

Reference is made to your November 5, 1996 fax requesting that certain clinical information be submitted.

In response to clinical request #3, please find enclosed a copy of Volume 25 of the Original NDA which contains the case report forms for patients who discontinued due to adverse events. Responses to the remaining clinical requests are being prepared and will be formally submitted to the NDA under separate cover.

If you have any questions regarding this submission, please contact me at (610) 454-5139.

Sincerely,

Audrey L. Hackman  
Senior Regulatory Affairs Associate  
Worldwide Regulatory Affairs

ALH/man  
Encl.

BP



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November 13, 1996

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



NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for  
Information  
- Pharmacology / Toxicology

Dear Dr. Wilkin,

Reference is made the November 5, 1996 fax from Ms. Olga Cintron which requested that certain clinical, biopharmaceutics, and pharmacology / toxicology information be submitted.

This submission consists of five volumes and contains the full study reports for the rat and mouse carcinogenicity studies, as well as the Canadian labeling requested in the above-mentioned correspondence. To facilitate the Agency's review, five copies of this submission are provided in the appropriate colored NDA jackets as follows:

- |                                |       |
|--------------------------------|-------|
| 1 Archival copy                | Blue  |
| 1 Pharmacology/Toxicology Copy | Gold  |
| 3 Statistical Copies           | Green |

This submission fully responds to the request for information to support the pharmacology / toxicology review of this NDA. Information responding to other requests will be submitted under separate cover. If you have any questions regarding this submission, please contact me at (610) 454-3026.

DATE	CSO INITIALS
MEMO <input type="checkbox"/>	LETTER <input type="checkbox"/>
	LETTER <input type="checkbox"/>
	MEMO <input type="checkbox"/>
	CSO ACTION
REVIEWS COMPLETED	

Sincerely,  
*Ronald F. Panner*  
Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

REVIEWS COMPLETED
CSO ACTION:
<input type="checkbox"/> LETTER <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS
DATE

RFP/alh/man  
Enclosures

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TEL. 610-454-8000

November 1, 1996

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 CORRESPONDENCE

NDA #20-743  
Noritate®(metronidazole 1% cream)

Response to FDA Request for  
Information

Dear Dr. Wilkin,

Reference is made to the above-mentioned original NDA submitted on September 30, 1996. Reference is also made to a telephone conversation earlier today in which Dr. James Vidra, Reviewing Chemist, requested that we confirm that the manufacturing facilities for the drug substance and drug product are ready for FDA inspection.

Please be informed that the manufacturing facilities for the drug substance and the drug product are ready for FDA inspection.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Encl.

REVIEWS COMPLETED
CSO ACTION:
<input type="checkbox"/> LETTER <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO



ORIGINAL  
NEW CORRESP

HC



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COLLEGEVILLE, PA 19426-0107  
TEL. 610-454-8000

October 28, 1996

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



NDA #20-743  
Noritate® (metronidazole 1% cream)

Response to FDA Request for  
Information

Dear Dr. Wilkin,

Reference is made to the above-mentioned original NDA submitted on September 30, 1996. Reference is also made to Ms. Mary Jean Kozma-Fornaro's subsequent telephone request that we formally submit certain information to the NDA to assist in the Pharmacology/Toxicology review of this application.

Therefore, please find enclosed the information requested by Ms. Kozma-Fornaro. The Agency's requests and Dermik responses are summarized on the pages which follow.

If you have any questions regarding this submission, please contact me at (610) 454-3026.

Sincerely,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

RFP/alh/man  
Enclosures

DUPLICATE



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A RHÔNE-POULENC RORER COMPANY

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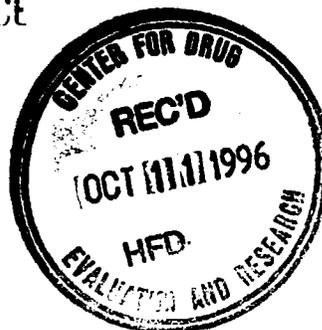
500 ARCOLA ROAD  
P.O. BOX 1200  
COLLEGEVILLE, PA 19426-0107  
TEL. 610-454-8000

October 10, 1996



NEW CORRESPONDENCE

Johnathan K. Wilkin, M.D., Director  
Division of Dermatologic and Dental  
Drug Products  
Attention: Document Control Room  
Food and Drug Administration  
Park Building, Room 214  
12420 Parklawn Drive  
Rockville, MD 20852



NDA 20-743  
Noritate®  
(metronidazole 1% cream)

Dear Dr. Wilkin:

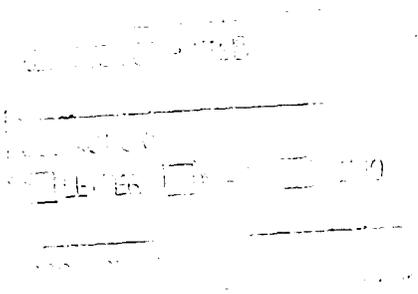
Reference is made to a telephone conversation I had earlier today with Project Manager, Ms. Olga Cintron, who requested the submission of six additional copies of the Summary volume (Vol. 1.1) of our NDA Noritate (metronidazole cream) Cream 1%.

Included in this submission are six copies of the Noritate Summary volume as requested.

Sincerely yours,

Ronald F. Panner  
Group Director  
Worldwide Regulatory Affairs

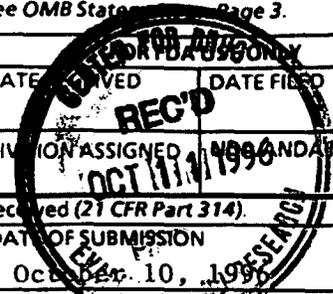
RFP/JPT/d  
Enclosures



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
**APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE  
 OR AN ANTIBIOTIC DRUG FOR HUMAN USE**  
*(Title 21, Code of Federal Regulations, 314)*

Form Approved: OMB No. 0910-0001.  
 Expiration Date: April 30, 1994.  
 See OMB Statewide Paper Reduction Project at [www.gsa.gov](http://www.gsa.gov) Page 3.

DATE RECEIVED DATE FILED  
 DIVISION ASSIGNED AND NO. ASS.



NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT  
 Dermik Laboratories, Inc.  
 ADDRESS (Number, Street, City, State and Zip Code)  
 500 Arcola Rd.  
 Collegeville, PA 19426

DATE OF SUBMISSION  
 October 10, 1996  
 TELEPHONE NO. (Include Area Code)  
 (610) 454-3026  
 NEW DRUG OR ANTIBIOTIC APPLICATION  
 NUMBER (if previously issued)  
 20-743

DRUG PRODUCT

ESTABLISHED NAME (e.g., USPI/USAN) metronidazole  
 PROPRIETARY NAME (if any) Noritate

CODE NAME (if any) n/a  
 CHEMICAL NAME 2-methyl-5-nitromidazole-1-ethanol

DOSAGE FORM cream  
 ROUTE OF ADMINISTRATION topical  
 STRENGTH(S) 1%

PROPOSED INDICATIONS FOR USE  
 Topical treatment of rosacea including inflammatory papules, pustules, and erythema

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21 CFR 314.420) REFERRED TO IN THIS APPLICATION:  
 IND  
 DMF  
 DMF  
 DMF

INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)  
 THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50)  THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION (Check one)

PRESUBMISSION  AN AMENDMENT TO A PENDING APPLICATION  SUPPLEMENTAL APPLICATION  
 ORIGINAL APPLICATION  RESUBMISSION

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION (e.g., Part 314.70(b)(2)(iv))

PROPOSED MARKETING STATUS (Check one)

APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx)  APPLICATION FOR AN OVER - THE - COUNTER PRODUCT (OTC)