CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-126/S-004

Trade Name: Zonalon

Generic Name: doxepin hydrochloride

Sponsor: Mylan Pharmaceuticals Inc.

Approval Date: August 1, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-126/S-004

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Reviews / Information Included in this NDA Review.

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Approvable Letter	
Labeling	
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Officer/Employee List	
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Medical Review(s)	
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APPLICATION NUMBER:

NDA 20-126/S-004

APPROVAL LETTER

19.1

AUG - 1 1996

NDA 20-126/S-004

GenDerm Corporation
Attention: Mr. Tom Stothoff
Regulatory Affairs Associate
600 Knightsbridge Parkway
Lincolnshire, Illinois 60069

Dear Mr. Stothoff:

Please refer to your supplemental New Drug Application (NDA) dated January 19, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zonalon (doxepin hydrochloride) Cream, 5%.

The supplemental application provides for approval of an additional package for the professional sampling of Zonalon Cream.

We have completed our review of this supplemental application and it is approved effective as of the date of this letter.

Revisions to the (b) (4) method are acknowledged and will be retained in our files.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

If you have any questions, please contact:

Mary Jean Kozma-Fornaro
Consumer Safety Officer
301/827-2020

Sincerely yours,

WHD 8/1/96

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, DNDC III
Division of Dermatologic
and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc: Original NDA 20-126
HFD-540/Division File
HFD-540/MJKozma-Fornaro
HFD-540/Pharm
HFD-540/MO
HFD-540/Chem/JDVidra
HFD-540/TeamLdr/WHDeCamp
HFD-80
HFD-232
DISTRICT OFFICE
HFD-222/New Drug Chemistry Division Director

APPROVAL

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APPLICATION NUMBER:

NDA 20-126/S-004

CHEMISTRY REVIEW(S)

DIVISION OF DERMATOLOGICAL AND DENTAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-126 **CHEM.REVIEW #:** SCS-004 **REVIEW DATE:** August 01,1996

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SUPPLEMENT/SCS-004	January 19,1996	February 01,1996	MAY 01, 1996

NAME & ADDRESS OF APPLICANT:
GenDerm Corporation
600 Knightsbridge Parkway
Lincolnshire, Illinois 60069
ATTN: Tom Stothoff
(847) 793-6148

DRUG PRODUCT NAME
Proprietary: Zonalon Cream
Nonproprietary/USAN: Doxepin Hydrochloride

Code Names/#'s: P-3693A/P-4599
Chemical Type/
Therapeutic Class:

ANDA Suitability Petition/DESI/Patent Status: Not Applicable

PHARMACOLOGICAL CATEGORY/INDICATION: moderate puritus, eczematous and atopic dermatitis and lichen simplex chronicus.

DOSAGE FORM: cream
STRENGTHS: 5 %
ROUTE OF ADMINISTRATION: topical
DISPENSED: X **Rx** _____ **OTC**

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

N,N-dimethyldibenz[b,e]oxepin-$\Delta^{11(6H)}$,γ-propylamine

Molecular Formula: $C_{19}H_{21}NO.HCl$
Molecular Weight: (b) (4)
CAS No.:

SUPPORTING DOCUMENTS:

NDA 20-126/SCS-004
IND (b) (4)
DMF
DMF
DMF

REMARKS/COMMENTS:

THIS N20-126/SCS-004 SUPPLEMENT IS APPROVED FOR USE AS AN ADDITIONAL SAMPLE PACKAGE SIZE (THREE GRAM (b) (4) TUBE) CONTAINING ZONALON CREAM.

REMARKS/COMMENTS (CONTINUED):

(b) (4)

[redacted]

Labeling for the new three gram professional sample was also found acceptable. The only labeling differences between the three gram and six gram samples were their: packaging size, NDC# and the six gram sample contained the manufacturer's name while the three gram sample had the marketer's name.

CONCLUSIONS & RECOMMENDATIONS:

This recommends FDA approval for accepting the use of a new three gram (b) (4) tube container containing Zonalon Cream. In addition, the (b) (4) its associated labeling have also met with acceptance.

James D. Vidra

James D. Vidra, Ph.D.
Review Chemist

cc: Orig. NDA 20-126
HFD-540/Division File
HFD-540/ProjMan/Kozma-Fornaro
HFD-540/Pharm/Shriver
HFD-540/Chem/Vidra JDV
HFD-540/Chem/WHDeCamp WHD 8/1/96
HFD-540/MedOffr/Toombs

filename: N20126S004

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APPLICATION NUMBER:

NDA 20-126/S-004

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date February 9, 1996

NDA No. 20-126

Tom Stothoff
GenDerm Corporation
600 Knightsbridge Parkway
Lincolnshire, IL 60069

Attention: Tom Stothoff

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Doxepin Hydrochloride Cream, 5%

NDA Number: 20-126

Supplement Number: S-004

Date of Supplement: January 19, 1996

Date of Receipt: February 1, 1996

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

Mary Jean Hasterlik

Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research

FORM FDA 3217d (12/91)

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