APPLICATION NUMBER:
NDA 20-126/S-004

Trade Name: Zonalon

Generic Name: doxepin hydrochloride

Sponsor: Mylan Pharmaceuticals Inc.

Approval Date: August 1, 1996
## Reviews / Information Included in this NDA Review.

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-126/S-004

APPROVAL LETTER
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,

[Signature]

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
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/DESJ/Patent Status: Not Applicable

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

DOSEAGE FORM:
cream
STRENGTHS:
5 %

ROUTE OF ADMINISTRATION:
topical

DISPENSED:
X Rx

OTC

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

N,N-dimethyldibenzo[b,e]oxepin-\Delta^{11(13)},\gamma-propylamine

Molecular Formula: C_{15}H_{21}NO.HCl

Molecular Weight: {\text{[8(4)]}}

CAS No.:

SUPPORTING DOCUMENTS:

NDA 20-126/SCS-004
IND
DMF
DMF
DMF

REMARKS/COMMENTS:

THIS N20-126/SCS-004 SUPPLEMENT IS APPROVED FOR USE AS AN ADDITIONAL SAMPLE PACKAGE SIZE (THREE GRAM [3(4)] TUBE) CONTAINING ZONALON CREAM.
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 tube container containing Zonalon Cream. In addition, the its associated labeling have also met with acceptance.

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
HFD-540/Chem/WHDeCamp
HFD-540/MedOffr/Toombs

filename: N201268004
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,  
[Signature]  
Supervisory Consumer Safety Officer  
Division of Anti-Infective Drug Products  
Center for Drug Evaluation and Research