Approval Package for:

APPLICATION NUMBER:

NDA 20-126/S-001

Trade Name: Zonalon

Generic Name: doxepin hydrochloride

Sponsor: Mylan Pharmaceuticals Inc.

Approval Date: May 1, 1995
## Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:
NDA 20-126/S-001

APPROVAL LETTER
Mr. Gary Knappenberger  
Director, Regulatory Affairs  
Genderm Corporation  
600 Knightsbridge Parkway  
Lincolnshire, Illinois 60069

Dear Mr. Knappenberger:

Please refer to your supplemental New Drug Application (NDA) dated May 5, 1994, 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 (b)(4)...

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

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

We note that one of the (b)(4)...

Similar observations for marketed should be reported as required by 21 CFR 314.81(b)(1)(ii).

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

Sincerely yours,

Wilson H. DeCamp, Ph.D.  
Supervisory Chemist  
Division of Topical Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research
cc: Orig: NDA 20-126
    HPD-540/Division File
    HPD-540/Higgins
    HPD-540/MI/Chambers
    HPD-540/Pharm/Alam
    HPD-540/CSO/Cook
    HPD-540/DeCamp
    R/D initialed by SUPV/CHM__

APPROVED
APPLICATION NUMBER:
NDA 20-126/S-001

CHEMISTRY REVIEW(S)
DIVISION OF TOPICAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-126  CHEM.REVIEW #: 01  REVIEW DATE: 24-APR-95
SUBMISSION/TYPEx DOCUMENT DATE  CDER DATE  ASSIGNED DATE
SUPPLEMENT/SCS-01  05-MAY-94  05-MAY-94  17-APR-95

NAME & ADDRESS OF APPLICANT: Genderm Corporation
600 Knightsbridge Parkway
Lincolnshire, IL 60069

DRUG PRODUCT NAME
Proprietary: Zonalon Cream
Nonproprietary/USAN: Doxepin Hydrochloride
Code Names/#'s:
Chemical Type:
Therapeutic Class:

PHARMACOLOGICAL CATEGORY/INDICATION: for the treatment of
the short-term (up to 8 days) management of moderate
pruritus in adult patients with the following forms of
eczematous dermatitis, atopic dermatitis and lichen simplex
chronicus.

DOSAGE FORM: cream
STRENGTHS: 5.0%
ROUTE OF ADMINISTRATION: Topical
DISPENSED: XXX Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
1-Propanamine, 3-dibenz(b,e)oxepin-11(6H)ylidene-N,N-
dimethyl-, hydrochloride

Refer to the USP for more details.

SUPPORTING DOCUMENTS:

IND - Acknowledged 12-11-89
DMF Type I, -- Type I DMFs are no longer reviewed by the reviewing chemist
DMF Type II, -- Reviewed on Aug. 5, 1994 and found adequate by
Doxepin HCl Cream, 5%

DMF Type I; Manufacturing site, facilities, personnel, and general operating -- Type I DMFs are no longer reviewed by the reviewing chemist.

REMARKS/COMMENTS:

This supplement was submitted to the subject of a New Drug Application to provide for

The supplement includes a

This acceptable.

However it should be noted that on page 113 of the

CONCLUSIONS & RECOMMENDATIONS:

This supplemental application is recommended for APPROVAL.

Janet G. Higgins
Review Chemist

cc: Orig. NDA 20-126
HFD-540/Division File
HFD-540/Higgins
HFD-540/MO/Tcombs
HFD-540/Pharm/Alam
HFD-540/CSO/Cook
HFD-540/SUPERVISOR/ De Camp
R/D Init by: SUPERVISOR

filename: N20126.S001