

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**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

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

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

**APPROVAL LETTER**

NDA 20-126/S-001

MAY 1 1995

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 [REDACTED] (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 [REDACTED] (b) (4)

[REDACTED] Similar observations for marketed [REDACTED] (b) (4)  
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,

*WD 5/1/95*  
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  
HFD-540/Division File  
HFD-540/Higgins *gbl 5/1/95*  
HFD-540/MO/Chambers  
HFD-540/Pharm/Alam  
HFD-540/CSO/Cook  
HFD-540/DeCamp  
R/D initialed by SUPVCHEM \_\_\_\_\_

APPROVED

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

**CHEMISTRY REVIEW(S)**

APR 24 1995

**DIVISION OF TOPICAL DRUG PRODUCTS**  
Review of Chemistry, Manufacturing, and Controls

**NDA #:** 20-126 **CHEM.REVIEW #:** 01 **REVIEW DATE:** 24-APR-95

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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 (b)(4)  
(b)(4) - Acknowledged 12-11-89

DMF (b)(4) Type I, (b)(4)  
(b)(4) -- Type I DMFs are no longer reviewed by the reviewing chemist

DMF (b)(4) Type II, (b)(4)  
(b)(4) -- Reviewed on Aug. 5, 1994 and found adequate by

NDA 20-126/SCS-001  
Genderm  
Doxepin HCl Cream, 5%

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DMF (b) (4) Type I, (b) (4); 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 (b) (4)

The supplement includes a (b) (4) (b) (4)

This (b) (4) acceptable.

However it should be noted that on page 113 of the (b) (4)

CONCLUSIONS & RECOMMENDATIONS:

This supplemental application is recommended for APPROVAL.

*Janet G. Higgins* 4/24/95

Janet G. Higgins  
Review Chemist

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

*WJD* 4/24/95

filename: N20126.S001