

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-126/S-002

Trade Name: Zonalon

Generic Name: doxepin hydrochloride

Sponsor: Mylan Pharmaceuticals Inc.

Approval Date: November 30, 1994

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APPLICATION NUMBER:
NDA 20-126/S-002

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APPLICATION NUMBER:
NDA 20-126/S-002

APPROVAL LETTER

12.1
NDA 20-126/S-002

Genderm Corporation
600 Knightsbridge Parkway
Lincolnshire, Illinois 60069

NOV 30 1994

Attention: Gary Knappenberger

Dear Mr. Knappenberger:

Please refer to your supplemental New Drug Application (NDA) dated June 2, 1994, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zonalon (doxepin hydrochloride) Cream, 5.0%.

We also acknowledge receipt of your submissions dated September 23, 1994 and September 27, 1994.

The supplemental application provides for a change in the

(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 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,

WA 11/29/94
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
HFD-540/MO/Chambers *PA 11/29/94*
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-002

CHEMISTRY REVIEW(S)

NOV 23 1994

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

NDA #: 20-126 **CHEM.REVIEW #:** 01 **REVIEW DATE:** 03-OCT-94

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
SUPPLEMENT/S-002	02-JUN-94	03-JUN-94	06-SEPT-94

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

DRUG PRODUCT NAME

<u>Proprietary:</u>	Zonalon Cream
<u>Nonproprietary/USAN:</u>	Doxepin Hydrochloride
<u>Code Names/'s:</u>	
<u>Chemical Type/</u>	
<u>Therapeutic Class:</u>	

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.

<u>DOSAGE FORM:</u>	cream
<u>STRENGTHS:</u>	5.0%
<u>ROUTE OF ADMINISTRATION:</u>	Topical
<u>DISPENSED:</u>	xxx Rx _____ OTC

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

1-Propanamine, 3-diebenz(b,e) oxepin-11(6H) Ylidene-N,N - dimethyl-, Hydrochloride

Refer to the USP for more details.

SUPPORTING DOCUMENTS: n/a

REMARKS/COMMENTS:

This supplement was submitted to the subject of a New Drug Application to provide for a change in the (b) (4) b

The proposed finished product (b) (4)

(b) (4)

NDA 20-126/S-002
Genderm Corporation
Zonalon Cream

page 2 of 2

(b) (4)

(b) (4) is acceptable and the recommendation of drafting an approvable letter is proposed.

CONCLUSIONS & RECOMMENDATIONS:

This supplemental application is recommended for APPROVAL.

Janet G. Higgins 10/3/94

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 *WDA 11/2/94*
filename:N20126.S002

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APPLICATION NUMBER:
NDA 20-126/S-002

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

MEMORANDUM OF A TELEPHONE CONVERSATION

September 23, 1994

Between: Gary Knappenberger

(b) (6)

And: Janet G. Higgins
HFD-540

Subject: Comments Regarding Information to be reported on
stability data charts

Further clarification of the dates of manufacturing and testing were requested for the (b) (4) of cream which were tested. The sponsor was also requested to include this data in following stability data which will be reported in each annual report of this application.

cc: Orig. NDA 20-126
HFD-540/Division File
HFD-540/Higgins
HFD-540/MO/Toombs
HFD-540/Pharm/Alam
HFD-540/Micro/Soprey
HFD-540/CSO/Cook
HFD-540/SUPERVISOR/De Camp
R/D Init by: SUPERVISOR
filename:N20126.S002

