CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 19-599/S-007

Trade Name: Naftin

Generic Name: naftifine hydrochloride

Sponsor: Merz Pharmaceuticals LLC.

Approval Date: June 4, 2002

Indication: For the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism *Trichophyton rubrum*.

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APPLICATION NUMBER:

NDA 19-599/S-007

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APPLICATION NUMBER:

NDA 19-599/S-007

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-599/S007

Allergan
Attention: Stephen Buxbaum
Director, Worldwide Regulatory Affairs
2525 Dupont Drive
P. O. Box 19534
Irvine, CA 92623-9534

Dear Mr. Buxbaum:

Please refer to your supplemental new drug application dated November 20, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Naftin (naftifine hydrochloride) 1% Cream.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (b) (4) as a contract manufacturer to replace all manufacturing operations for this product previously conducted by Allergan at the Irvine, CA, facility. This supplemental new drug application also provides for a change in tube sealant from (b) (4). In addition, as part of this manufacturing site change, (b) (4) will perform all necessary testing for raw material, component and finished product release and ongoing stability testing.

We have completed the review of this supplemental application, and it is approved.

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

If you have any questions, call Frank H. Cross, Jr., Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products, (HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Wilson H. DeCamp
6/4/02 02:33:38 PM
approved

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 19-599/S-007

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW | 1. **ORGANIZATION** DDDDP (HFD-540) | 2. **NDA NUMBER** 19-599

3. **NAME & ADDRESS OF APPLICANT**

Allergan
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

4. **AF NUMBER**

5. **SUPPLEMENT(s) NUMBER(s)DATE(s)**
SCM-007 11/20 /02

6. **NAME OF DRUG**
Naftin

7. **NONPROPRIETARY NAME**
naftifine hydrochloride

8. **SUPPLEMENT(s) PROVIDES FOR:**

9. **AMENDMENTS AND OTHER (REPORTS, etc.) DATES**
none

[redacted](b) (4) as contract manufacturer for finished drug product and a change in tube sealant from [redacted](b) (4)

10. **PHARMACOLOGICAL CATEGORY**

11. **HOW DISPENSED**
X Rx OTC

12. **RELATED IND/NDA/DMF(s)**

13. **DOSAGE FORM(s)**
Cream

14. **POTENCY(ies)**
1%

15. **CHEMICAL NAME AND STRUCTURE**

m.w. .
CAS Registry No. - -

16. **RECORDS AND REPORTS**
CURRENT
x Yes No
REVIEWED
x Yes No

17. **COMMENTS**

Allergan provides for [redacted](b) (4) as contract manufacturer of Naftin (naftifine hydrochloride) 1% Cream. [redacted](b) (4) replaces the previously approved manufacturing site for Allergan at the Irvine facility. [redacted](b) (4) will performed all of the testing for the raw materials, drug substance, finished product and ongoing stability studies in accordance with the NDA, and post approval commitments.

[redacted](b) (4) is an established manufacturing facility for other pharmaceuticals. [redacted](b) (4)

In addition, Allergan proposed a change in the tube sealant from (b) (4) According to Allergan, this sealant was approved for use with other Allergan marketed products, e.g., FML (flourometholone ophthalmic ointment) 0.1%, NDA 17760; PREG-G (prednisolone acetate, gentamicin sulfate) S.O.P. sterile ophthalmic ointment, etc.

In support of this supplement, the following information was submitted:

(b) (4)

18. **CONCLUSIONS AND RECOMMENDATIONS**
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 19-599

HFD-540	HFD-540/Vaughan
HFD-540/Mainigi	HFD-540/Cross
HFD-5420/EGPappas	HFD-540/WHDeCamp: R/D initialed __

19. **REVIEWER**

NAME	SIGNATURE	DATE COMPLETED
Ernest G. Pappas		6/03/02

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

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/s/

Ernest G. Pappas
6/4/02 10:07:28 AM
CHEMIST
Recommend approval of supplement.

Wilson H. DeCamp
6/4/02 01:10:01 PM
CHEMIST
concur with review; AP letter may be prepared