CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-124

MICROBIOLOGY REVIEW

NDA 21-124
1% terbenafine hydrochloride solution
Novartis Pharmaceutical Corp.

MOL. WT.
327.90

DOSAGE FORMS: Solution

STRENGTH: 1%

ROUTE OF ADMINISTRATION: Topical

PHARMACOLOGICAL CATEGORY: Antifungal

DISPENSED: OTC

INITIAL SUBMISSION:
Received by CDER: 5/17/99
Received by Reviewer: 6/22/99
Review Completed: 11/2/99

AMENDMENTs: None

RELATED DOCUMENTS:

NDA 20-192 (1% cream), NDA 20-539 (Lamisil Tablets), NDA 20-749 Lamisil solution/spray 1%), NDA 20-846 (Dermgel 1%), NDA 20-940 (Hydrochloride Cream 1%)

CONSULTS:
None

REMARK(S):
The product was approved as NDA 20-749 on October 17, 1997 for perscription usage for interdigital tinea pedis, tinea corporus, tinea cruris, and tinea vesicolor. The OTC submission includes these indications with the exception that tinea vesicolor will remain as a perscription indication only. At the pre-NDA meeting of December 21, 1998 it was decided that, " with the exception of safety data, no additional studies beyond those already submitted under NDA 20-749 in support of the proposed over-the-counter status of Lamisil Solution, 1%

in adult patients are needed." Therefore, no new microbiology data was submitted for analysis. Because of technical and time restraints, no new microbiological data will be submitted as part of the annual report for NDA 20-749.

CONCLUSIONS and/or RECOMMENDATIONS:
A complete clinical microbiological review was conducted by Dr. Sousan Altaie as required for NDA 20-749. The product was approved for the treatment of tinea cruris, tinea pedis and tinea corporis as well as tinea vesicolor (which will remain as perscription only). Sufficient data to support the treatment of organisms that are common causes of the three indications considered for RX-OTC switch were presented and appproved by Dr. Altaie and subsequently listed in the labeling for perscription usage-NDA 20-749. Since there are no new microbiological data or issues and since the clinical indications are easy to recognize by patients and treated by several other OTC products including various other Lamasil formulations, the switch of terbenafine hydrochloride solution,1% to non-perscription status is approved from the clinical microbiological point of view.

/S/
Joel Unowsky, Ph.D.
Microbiology Reviewer

cc: Orig. NDA # 21-124
Joel Unowsky
Microbiologist, HFD-520

concurrence only:

SMicro/Asheldon RD and Final Signed 11/3/99 CSO
11/4/99

/S/ 11/5/99
DepDir/Lgavrilovich

CSO: Frances LeSane

cc: Orig. NDA # 21-124
HFD-540/Frank Cross

/S/ 3/17/00

NDA 21-124
1% terbenafine hydrochloride solution
Novartis Pharmaceutical Corp.

NOV 4 1999

[Consultative Review to HFD 540, RX to OTC switch..]

Division of Anti-Infective Drug Products (HFD-520)

Clinical Microbiology Review Notes #1

NDA # 21-124 **DATE COMPLETED: 11/2/99**

APPLICANT(NDA): Novartis Pharmaceutical Corporation
59 route 10
East Hanover, New Jersey
07936-1080

CHEM/THER. TYPE: Antifungal, Allylamine derivative, 1S

SUBMISSION REVIEWED: NDA, RX-OTC switch
PROVIDING FOR: Treatment of interdigital Tinea Pedis, Tinea corporis, Tinea Cruris

PRODUCT NAMES(S):
Proprietary: Lamisil

Non-Proprietary/USAN: Terbenifine Hydrochloride

Code Name or Number: None

CHEMICAL NAME:
(E)-N-(6,6-dimethyl-2-heptene-4-ynl-N-methyl-naphthalenemethanamine hydrochloride)

STRUCTURAL FORMULA:
See USP Dictionary, 1996, page 685.

MOLECULAR FORMULA:
$C_{21}H_{26}ClN$