



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

7/22/97
M645N

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

July 22, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-3905

Telephone: (913) 752-2100

WARNING LETTER

Mr. James A. Zargo, President
McCormick Distilling Co.
One McCormick Lane
Weston, MO 64098

Ref.# - KAN-97-022

Dear Mr. Zargo:

This letter is in reference to your firm's marketing and distribution of Sep-T-Ban[®], a topical product promoted as a virucidal. Your labeling claims "Sep-T-Ban[®] kills 100% of detectable ... Hepatitis A, Influenza A2 (HK flu), HIV-1 (AIDS Virus), Herpes Simplex Type II, Polio I Virus, Cocksackie Virus B5a, and *Trichophyton mentagrophytes*."

These claims cause this product to be a drug as defined under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Sep-T-Ban[®] is also a "new drug" under Section 201(p) of the Act, because this product is not generally recognized as safe and effective for its intended uses. Since this drug is a "new drug", it may not be marketed in the United States without an approved new drug application as is required under Section 505(b) of the Act.

Your product is also subject to the monograph for "Antifungal active ingredients" under Title 21 Code of Federal Regulations, Section 333.210, since your labeling claims Sep-T-Ban[®] is effective against *Trichophyton mentagrophyte*, a fungus. Sep-T-Ban[®] does not comply with the monograph and is also a new drug for this claim.

In addition, the product is misbranded under Section 502(f)(1) because its labeling fails to bear adequate directions for use. Its labeling is false and misleading since it suggests that the product is safe and effective and this has not been established.

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McCormick Distilling Co.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. Such actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Mr. Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

Orig.: Addressee
bcc: LE; FF(1912744); HFA-224; HFD-314 (Russell); HFI-
35/DIB(via FOI); HFC-210; GDD; RF

CRP:jl