



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

March 5, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 11

Charles W. Herbster
President/CEO/CFO
Conklin Company, Inc.
551 Valley Park Drive
Shakopee, Minnesota 55379

Dear Mr. Herbster:

This letter concerns *Fortress® Protective Skin Cream* currently marketed by your firm for over-the-counter (OTC) drug uses. Based on information obtained during an inspection of your firm at the address noted above, this product is intended for OTC skin protectant uses. It is also intended for repeated applications to bond to, and form an impervious barrier on, human skin for the purpose of providing continuous long-term effectiveness in preventing harmful effects and diseases caused by contact with allergens (e.g., latex) and a broad range of other hazardous substances. These skin barrier uses are conveyed through representations, such as those that follow, which appear on the immediate container label and in promotional material (e.g., product catalog) that accompanies shipments of this product:

By forming a protective film on the skin's surface, Fortress may aid in preventing skin contact with irritants and chemicals. Use Fortress alone or apply it under latex or vinyl gloves to protect your skin from the irritation that gloves can cause.

"...protects your skin for up to four hours."

Based on these intended skin barrier uses and the skin protectant uses also found in the label and promotional material distributed with this product (i.e., "helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin"),

Page Two

Charles W. Herbster
March 5, 2003

Fortress® Protective Skin Cream is a “drug” as defined under Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

We are not aware of any substantial scientific evidence that *Fortress® Protective Skin Cream* is generally recognized by scientific experts as safe and effective for the skin barrier uses conveyed in the labeling. These uses are not being considered in any of the rulemakings under the Food and Drug Administration’s (FDA’s) OTC Drug Review. Therefore, *Fortress® Protective Skin Cream* is a “new drug” as defined by Section 201(p) of the Act. Because this product is not the subject of an FDA-approved new drug application (NDA), its current marketing in the United States by your firm violates Section 505(a) of the Act. In addition, *Fortress® Protective Skin Cream* is misbranded under Section 502(e) of the Act because the label does not identify the active ingredient(s).

For your information, FDA is presently evaluating the safety and effectiveness of skin protectants under the OTC Drug Review. A tentative final monograph (TFM) for such products was published in the Federal Register (FR) of February 15, 1983 (48 FR 6820). Products intended for skin barrier uses, like *Fortress® Protective Skin Cream*, are not included in this rulemaking. Pending a final monograph, FDA does not object to the marketing of products that meet both the formulation and labeling requirements, described in this proposed rule, and also comply with all existing regulations affecting these products [e.g., Title 21 of the Code of Federal Regulations, Part 201 (21 CFR 201) et al]. Such marketing, however, is subject to the risk that a final monograph or other final rule may require reformulation and/or relabeling or FDA approval through the “new drug” procedures of the Act (Section 505).

We would not object to the continued marketing of *Fortress® Protective Skin Cream*, as presently formulated, for the skin protectant uses currently represented in the labeling, i.e., “...helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin.” These uses are covered by the rulemaking under the OTC Drug Review for skin protectants, like *Fortress® Protective Skin Cream*, that contain dimethicone as the active ingredient. (See 48 FR 6820.) Compliance with the future final monograph for OTC skin protectants may require that *Fortress® Protective Skin Cream* be reformulated and/or relabeled or approved through the NDA procedures to be legally marketed in the United States.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do so may

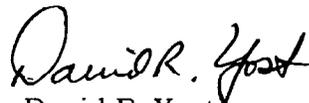
Page Three

Charles W. Herbster
March 5, 2003

result in regulatory action without further notice, including seizure and/or injunction.

Please respond to this office in writing within 15 working days of receiving this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations described above. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be sent to Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,



David R. Yost
Acting Director
Minneapolis District

xc: 