



Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

August 24, 2000

Ref: 2000-DAL-WL-15

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Lester A. Levy
Chairman of the Board
NCH Corporation
2727 Chemsearch Boulevard
Irving, Texas 75062

Dear Mr. Levy:

This letter concerns the over-the-counter (OTC) marketing and promotion of "DERMACOAT™ Skin Protectant Hand Cream," by your firm. During an inspection of Mohawk Laboratories, your own-label distribution facility, on April 26, May 18, June 1 and 2, 2000, our investigator obtained an immediate container label and promotional labeling for this product. Promotional labeling includes a flyer (Tech Sheet, Revision 9M701) used, in whole or in part, by sales representatives to promote the product.

Based on the label and labeling, this product is intended to form an invisible "barrier" on the skin. It is labeled and promoted for long term effectiveness equivalent to the protection provided by gloves in preventing adverse effects and diseases caused by various harmful or caustic substances (e.g., mild acids and alkalis, paints, oils, plastics, inks, tars, resins, greases, epoxies, solvents, and other industrial materials). Thus, "DERMACOAT™ Skin Protectant Hand Cream," is a "drug" as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The intended uses described above are conveyed through the product's name as well as statements, claims, and representations made on immediate container labels and promotional labeling, which include:

" . . . DERMACOAT™. . . Let dry to a final barrier coat . . . forms an invisible barrier that temporarily protects the skin by sealing out many mild acids and alkalis, paints, resins, epoxies, plastics, inks, tars and salts as well as other oil-soluble or water-soluble irritants. . . forms an invisible barrier against skin irritations. . . It coats and shields the skin from exposure to alkalis, paints, oils, and other potentially irritating

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substances...PROTECTS LIKE A GLOVE – Helps prevent skin irritations from mild acids and alkalis, paints, oils, plastics, inks, tars, resins, greases, epoxies, solvents and other industrial materials...LONG LASTING...does not have to be constantly reapplied....”

From a review of the information, the respective product formulations and labeling obtained during our inspection, we have determined that “DERMACOAT™ Skin Protectant Hand Cream,” does not qualify for evaluation under the ongoing OTC Drug Review being conducted by the Food and Drug Administration (FDA). Representations of any kind for prophylactic “barrier” or “shield” uses, including representations to protect against adverse effects and diseases caused by allergens, pathogens, or other hazardous substances such as those noted above, are not described in any of the rulemakings being considered under the Review. We are also not aware of any substantial scientific evidence that these drug products, as formulated and labeled, are generally recognized among scientific experts as safe and effective for these labeled uses. Thus, “DERMACOAT™ Skin Protectant Hand Cream,” is a “new drug” as defined by section 201(p) of the Act and may not be legally marketed in the United States without an approved new drug application (NDA) under section 505(a) of the Act.

In addition, since the adequacy of the labeled directions for this “barrier” or “shield” use has not been established, this product is misbranded under section 502(f)(1) of the Act. 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.

You should immediately inform all contract manufacturers and any sub-distributors of FDA’s determination, regarding the regulatory status of these products, by sending each of them a copy of this Warning Letter. You should also advise them of the steps you are taking and identify the steps they should take to correct the violations described above.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, and what you have instructed your contract manufacturers and any sub-distributors to do 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 fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

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Your reply should be directed to Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director