



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
Food and Drug Administration
Atlanta District Office *RSO*

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60 8th Street, N.E.
Atlanta, Georgia 30309

August 2, 1999

VIA FEDERAL EXPRESS
RETURN RECEIPT REQUESTED

Kevin Gallagher
President/CEO
Amrep, Inc.
990 Industrial Park Drive
Marietta, Georgia 30062

WARNING LETTER
(99-ATL-25)

Dear Mr. Gallagher:

This letter concerns MISTY® Barrier Cream, [REDACTED] SHIELD SKIN PROTECTOR, and [REDACTED] SKIN PROTECTION FOR WRESTLERS, manufactured and marketed by your firm. During an inspection of your facility on June 10 and 11, 1999, Investigator Leah M. Andrews obtained information and labeling for these products. Based on that information and labeling, these products are intended to form a continuous layer or "barrier" on the skin. They are offered for long-term effectiveness on the skin to prevent diseases caused by exposure to various chemical compounds (including solvents and lubricants) or to biological materials and/or pathogenic microorganisms associated with "waste water," "marine industries," "laboratory" environments or through human contact (e.g., wrestling). Thus, these products are "drugs" as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The intended uses described above are conveyed through trade names, labeling, and promotional statements, including: "... Barrier Cream ...," "... SHIELD ...," "... The highly protective, invisible cream is used for up to four hours of skin protection against ... chemicals, liquids and other agents that may normally be harmful to the skin ...," "... dispense a few drops of hydrochloric acid (Bolex) into the palm of your hand ... even this aggressive acid does not penetrate our protective coating ...," and "... help protect the wrestler from the unwanted problems which can arise from contact with other wrestlers or unclean surfaces...."

From a review of the information and labeling provided, we have determined that MISTY® Barrier Cream, [REDACTED] SHIELD SKIN PROTECTOR, and [REDACTED] SKIN PROTECTION FOR WRESTLERS do not qualify for evaluation under the ongoing Over-the-Counter (OTC) Drug Review being conducted by the Food and Drug Administration (FDA). Representations for prophylactic "barrier" uses, 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 products are generally recognized among scientific experts as safe and

effective for these uses. Thus, such products are "new drugs" as defined by section 201(p) of the Act and they 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 these "barrier" uses has not been determined, these products are misbranded under section 502(f)(1) of the Act. They are also misbranded under section 502(o), because they have not been manufactured by a registered facility nor listed with FDA as required by section 510 of the Act.

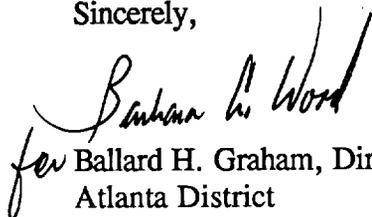
For your information, the proposed labeling for [REDACTED] SKIN PROTECTION, which was given to Investigator Andrews during her inspection, does not conform to the labeling for "skin protectant" drug products covered under the OTC Drug Review. Specifically, the statement, "... protects exposed skin surfaces from harmful or annoying stimuli ..." is not being proposed under the Review for labeling OTC "skin protectants." Considering (1) the prominent placement of this statement on the proposed labeling and (2) the statement, "... [REDACTED] was designed for wrestling where skin protection is essential..." which appears elsewhere on the labeling, [REDACTED] SKIN PROTECTION is represented for the same prophylactic "barrier" uses for which [REDACTED] SKIN PROTECTION FOR WRESTLERS is being offered, i.e., to provide protection against hazardous biological materials and/or pathogenic microorganisms. We note further that the term "SHIELD" in the name [REDACTED] also represents the product as a skin "barrier." As explained above, OTC skin "barriers" are not covered under the OTC Drug Review and require NDA approval before marketing in this country. Please take this into consideration

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 regarding drugs and devices so that they may take this information into account when considering the award of contracts.

Federal agencies are advised of the issuance of all warning letters about drugs 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 result in regulatory action without further notice. This action may include seizure and/or injunction.

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, to correct the violations. Your response 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. Your reply should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely,


for Ballard H. Graham, Director
Atlanta District