



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

December 11, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert A. Hills
President
Evolve, Inc.
411 West 400 South
Salt Lake City, Utah 84101

PURGED

Ref. # DEN-98-3

WARNING LETTER

Dear Mr. Hills:

This letter concerns your firm's marketing and over-the-counter (OTC) distribution of the product OVERHAND SKIN SEALANT FORMULA (OVERHAND). During an inspection of your establishment by the U. S. Food and Drug Administration (FDA) on July 23, 1997 and December 2, 1997, samples of the marketed product and accompanying promotional labeling, which includes brochures and fliers, were collected.

As described in its labeling, OVERHAND cream is intended to form a sealant or barrier on human skin that is impenetrable to nearly everything to which it is exposed, including various harsh or toxic chemicals (e.g., organic and inorganic acids and bases, solvents, epoxy resins, and talc), allergens or sensitizers (e.g., poison ivy, drugs, latex, and rubber additives), body fluids (e.g., blood and urine), and a broad spectrum of bacteria, fungi, and viruses (including blood-borne pathogens such as the Human Immunodeficiency Virus (HIV)). The labeling states that this barrier is useful in preventing contact and chronic dermatitis, skin infections and other diseases caused by bacteria, fungi, and viruses (including Acquired Immune Deficiency Syndrome (AIDS)), athlete's foot and other fungal infections. In addition, the labeling claims that this product is useful in the treatment of sunburn, for itching, and for treating and preventing decubitus ulcers. The labeling also claims that OVERHAND provides long-term effectiveness for four to six hours, and that its effectiveness is not diminished by repeated washings with soap and water or by exposure to temperature up to 150°F.

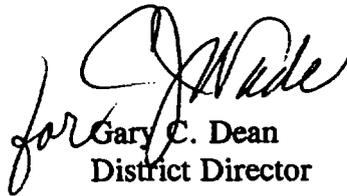
Based on the intended uses described above, OVERHAND is a "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This product is offered for treating and/or preventing many varied diseases for which there is no substantial scientific evidence of safety and effectiveness. In addition, though OVERHAND claims to be useful in treating and preventing athlete's foot, it does not conform with the final monograph for OTC topical antifungal drug products as referenced in 21 CFR 333.201. Therefore, OVERHAND is a "new drug," as described in section 201(p) of the FFDCA, which may not be legally marketed in the United States without an approved new drug application under section 505(a) of the FFDCA. OVERHAND is also misbranded under section 502(f)(1) of the FFDCA, because it does not bear adequate directions for the uses described above.

This letter is not intended to be a comprehensive review of the above named product or any other products marketed by your firm. It is your responsibility to assure that all requirements of the FFDCA and pertinent regulations are being met. You should take prompt action to correct these violations. Federal agencies are routinely advised of the issuance of Warning Letters so that they may take this information into account when considering the award of government contracts.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to correct the violations described above. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The FFDCA provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products under section 304 and 302, respectively.

Please send your reply to Ms. Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,


Gary C. Dean
District Director

cc:

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