DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 13 1992

WARNING LETTER

Ref. No. HFD-312-09

RECEIVED
MAY 21 1992
SEA-DO-C/B

Adele Vadas, Manager
Global Esthetics
Suite 876, Box 34069
Seattle, Washington 98124

Dear Ms. Vadas:

This is in reference to the marketing of "PEELAWAY FACIAL SYSTEMS" such as the "PEELAWAY FORMULA 1000", "PEELAWAY FORMULA 2000", "PEELAWAY FORMULA 3000" and the "PEELAWAY - BODY PEEL FORMULA" by your firm. Labeling, which includes the brochure "Discover the Scientific Solution for Beautiful Skin", contains certain statements that represent and suggest that the above products are useful in treating or preventing acne and other skin irregularities. Such statements include, but are not limited to, "...Skin thickening is responsible for the majority of wrinkles and the aged appearance. The thickened skin can be blotchy, blemished and unattractive. The cellular debris associated with this skin can plug pores and interfere with the natural functions of the skin, creating blemishes, blackheads, whiteheads and acne conditions...Facial Peeling thins the outer layers...restore its natural thickness...Peelaway Facials will improve...the following conditions: WRINKLES, LINES, ACNE SCARS, CREPEY SKIN, UNEVEN SKIN TONES, BLOTCHES, BLEMISHES, BLACKHEADS, LARGE PORES, BROWN SPOTS, AGE SPOTS, WHITEHEADS, MINOR FACIAL SAGGING, MOTTLING and other complexion irregularities...".

Because such labeling includes statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body, the products are drugs within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). The products are also subject to the Final Rule (in the form of a Final Monograph on Topical Acne Drug Products for Over-the-Counter Human Use), as codified in Title 21, Code of Federal Regulations, Part 333.301 which published in the FEDERAL REGISTER of August 16, 1991. This Final Rule becomes effective August 16, 1992. A drug subject to this Final Rule that is initially introduced or initially delivered for introduction into interstate commerce on or after the effective date of the regulation must be in compliance with the regulation unless it is the subject of an approved new drug application (NDA).

Under the agency's general regulatory policy governing OTC products during the pendency of the OTC Review, OTC products may be permitted to be marketed without risk of regulatory action provided:

1. The product or similarly formulated and labeled products were marketed as OTC drugs at the inception of the OTC Review (May 11, 1972), a date that was then extended to on or before December 4, 1975 (21 CFR 330.13).

2. Such product does not constitute a hazard to health.

3. The product formulation is not regarded to be a prescription drug within the meaning of 503(b).

4. It is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

The "DIRECTIONS FOR PEELAWAY PATCH TEST" states the ingredients in the "PEELAWAY" products are "water, citric acid, malic acid, glycolic acid, ascorbic acid, lactic acid, salicyclic acid, papain, calcium pantothenate, acetic acid, resorcinol and fragrance". The agency's analysis of your product revealed the product did not contain glycolic acid and lactic acid. However, it did contain phenol at 6.8%, which is not declared.

The Food and Drug Administration is aware of several adverse reaction reports of severe burning, swelling and pain associated with the use of the "PEELAWAY FACIAL SYSTEMS". The agency has also received letters from licensed practitioners reporting that consumers have found it necessary to seek medical attention to resolve the health problems associated with the use of your product. Based on the evaluation of these reports the agency has concluded that a health hazard exists which warrants the removal of such drugs from the marketplace prior to the effective date of 21 CFR 333.301.

In addition, we are unaware of any substantial scientific evidence which documents that these drugs are generally recognized as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling. The drugs are therefore, new drugs within the meaning of Section 201(p) of the Act. Accordingly, "PEELAWAY FORMULA 1000", "PEELAWAY FORMULA 2000", "PEELAWAY FORMULA 3000" and "PEELAWAY BODY PEEL FORMULA" may not be introduced into interstate commerce under section 505(a) of the Federal Food, Drug, and Cosmetic Act, since they are new drugs within the meaning of section 201(p) of the Act and no approval of an application filed pursuant to section 505(b) is effective for such drugs.

The above referenced articles are also misbranded within the meaning of section 502(f)(1) of the Act in that the labeling fails to bear adequate directions for use for the conditions for which they are offered and they are not exempt from this requirement under regulation 21 CFR 201.115 since they are unapproved new drugs.

The articles are further misbranded within the meaning of sections 502(a) and 502(e) of the Act in that the declared ingredients differ from those which are actually contained in the products, and all the active ingredients are not declared on the immediate container labels.

The above listed deficiencies should not be construed as all inclusive of those violations which may exist in your firm. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder are being met.

We request you reply within five (5) days of your receipt of this letter stating the action you will take to discontinue the marketing of these drugs. If stocks of these products and promotional materials remain in trade channels at this time, we request that they be immediately recalled to the retail level. Failure to cease distribution immediately may result in regulatory action without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products (section 304) and for injunction (section 302) against the manufacturer or distributor of illegal products.

Your reply should be directed to:

Kim C. Kunzig-Loff, National Coordinator
OTC Compliance Branch (HFD-312)
Division of Drug Labeling Compliance
5600 Fishers Lane
Rockville, Maryland 20857

Sincerely yours,

Daniel L. Michels
Director, Office of Compliance
Center for Drug Evaluation and Research

cc: Global Esthetics
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