



U.S. Food and Drug Administration

New York District
850 Third Avenue, Brooklyn, New York 11232

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Leonard Lauder, President
Estee Lauder Companies, Inc.
767 Fifth Avenue
New York, New York 10153

December 15, 1997

re: 11-NYK-98

Dear Mr. Lauder:

As a result of a September 17 and 23, 1997 inspection of your facility at New York and Melville, and through other sources, we have determined that your firm is currently marketing "CLINIQUE exceptionally soothing cream for upset skin", and "CLINIQUE exceptionally soothing lotion for upset skin". Both products are labeled to contain hydrocortisone acetate as the active ingredient, and are labeled as a "Calming influence for any skin when it over-reacts to stress, weather, pollutants. Rushes soothing care to sensitized skin. Helps comfort and de-itch. Special ingredients work to strengthen skin against further damage from external irritants. This product contains hydrocortisone which Clinique's dermatologists have found to be especially beneficial to uncomfortably irritated skin."

These products are drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in the treatment or prevention of disease in man, or they are intended to affect the structure or function of the body of man. Further, "Hydrocortisone Acetate Cream", and Hydrocortisone Acetate Lotion" are found in the United States Pharmacopoeia (U.S.P. 23), an "official compendium", as this term is defined in section 201(j) of the Act. Accordingly, marketing of these drugs is a violation of the Act as follows:

Part 1, Drug Requirements.

These drugs are misbranded within the meaning of section 502(e)(1) and regulation 21 CFR 202.61 in that their label fails to bear the established name of the drug (hydrocortisone acetate cream or hydrocortisone acetate lotion).

These drugs are misbranded within the meaning of section 502(g) of the Act in that each purports to be a drug the name of which is recognized in an official compendium, and they fail to be packaged and labeled as prescribed therein. The following labeling violations are noted:

- The labeling for your products fails to state the amount or percentage of the active ingredient, hydrocortisone acetate, which requirement is as stated in the U.S.P. 23 General Notices under *Labeling*, pages 11 and 12. Ms. Nancy M. Loudon, Associate Counsel, Clinique Laboratories, Inc., in a September 26, 1997 letter to New York District Consumer Safety Officer Valerie Grecek-Trinh, states that each product contains "a half percent of hydrocortisone" and is to be sold by a trained Clinique consultant only at Clinique cosmetics counters.
- The labeling for your products fails to state the expiration date, which requirement is as stated in the U.S.P. 23 General Notices under *Labeling*, page 12.

These drugs are further misbranded under section 502(o) of the Act in that you have not listed them with the FDA as required by section 510(j) of the Act.

Part 2, Special Drug Requirements.

Further, based on their intended uses, both products are external analgesic drug products for over-the-counter (OTC) human use, and are subject to coverage under the ongoing review of OTC human drugs. Hydrocortisone and hydrocortisone acetate are ingredients which, prior to December 4, 1975, were in drug products limited to sale only with a prescription. Conditions for marketing OTC drug products which contain an active ingredient which was previously restricted to prescription sale are detailed in 21 CFR 330.13(b)(2). This regulation states that such products are at risk for regulatory action if they are not formulated and labeled in accord with a proposed or tentative final monograph.

Statements found in the labeling for the two products are not in accord with the required labeling for OTC drug products containing 0.25 to 0.5% hydrocortisone or hydrocortisone acetate equivalent to 0.25 to 0.5% hydrocortisone, as provided for in the December 4, 1979 Advance Notice of Proposed Rulemaking (ANPR), the February 8, 1983 Tentative Final Monograph (TFM), the July 30, 1986, August 25, 1988, and February 27, 1990 amendments to the TFM, and the Notice of August 30, 1991 published in the **Federal Register**. Each of the articles is therefore a "new drug" within the meaning of section 201(p) of the Act. Because there is no approved New Drug Application filed pursuant to Section 505(b) or 505(j) in effect for these drugs, they may not be introduced or delivered for introduction into interstate commerce under section 505(a) of the Act.

Additionally, these drugs are misbranded under Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for use and they are not exempt from this requirement under 21 CFR Part 201.115, since they are new drugs.

The above cited violations should not be regarded as all inclusive. It is your responsibility to ensure that all requirements of the Federal Food Drug and Cosmetic Act and all regulations promulgated thereunder, are being satisfied for all products subject to these requirements.

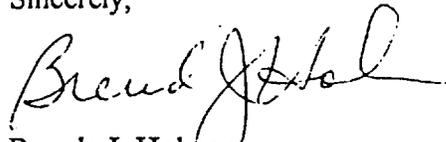
We have received a letter dated September 26, 1997 from your Associate Counsel, Ms. Loudon, which states that certain labeling revisions for the products will be made. It is our position that these corrections fail to bring the labeling into compliance because the insert continues to promote use of the product for, among other uses, skin irritation caused by weather, pollutants, stress, smoke, smog, soot, UV radiation, and additives.

We request that you take prompt action to correct these deviations. 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. Failure to promptly correct these deviations may result in regulatory action without further notice. This action may include seizure of illegal products (section 304 of the Act) and/or injunction (section 302 of the Act) against you and your firm.

We request that you notify this office in writing, within 15 working days of receipt of this letter, stating the specific steps you have taken to correct these violations. Please include an explanation of each step being taken to prevent the recurrence of similar violations and a timetable for correction.

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely,



Brenda J. Holman
District Director
New York District