



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service
Food and Drug Administration

MJL/BN

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

June 2, 1999

WL-32-9

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Donald Christal, President
California Sun Care, Inc.
10877 Wilshire Blvd., 12th Floor
Los Angeles, California 90024

Dear Mr. Christal:

This letter is in reference to the distribution, promotion, and marketing of various tanning accelerators and over-the-counter (OTC) sunscreen drug products by your firm. During an inspection of your facility located on the 12th floor of 10877 Wilshire Blvd., Los Angeles, California, conducted on February 11, 1999, FDA investigators documented that your firm was distributing a number of tanning accelerators and sunscreens. The tanning accelerators list "tyrosine" as an ingredient on the label and include labeling claims equivalent to the term "Accelerator" such as "Maximizer" or "Intensifier." The tanning accelerators include those labeled as "Polarity," "summer EXPOSURE," "tropical EXPOSURE," "MAXLOTION," "CuO2," "Vengeance," "Fever," "VERY HIGH OUTPUT," "Butter," "MOCHA," and "MAXGEL." The Sunscreens are labeled as "EMERALD BAY SPF 8" and "EMERALD BAY SPF 17."

The Food and Drug Administration states, on page 28293 of the Tentative Final Monograph for Sunscreen Drug Products for Over-the Counter Human Use published in the May 12, 1993 Federal Register (copy enclosed), that any product purporting to "accelerate the tanning process" or "stimulate the production of melanin" is claiming to affect the structure and function of the body and, therefore, is a drug [Section 201(g) of the Federal, Food, Drug, and Cosmetic Act (the Act)]. We are not aware of any data demonstrating that tyrosine or its derivatives are effective in stimulating the production of melanin. Thus, any product containing tyrosine or its derivatives and claiming to accelerate the tanning process is a "new drug" [Section 201(p) of the Act] which may not be legally marketed in this country without an approved New Drug Application (NDA) [Section 505(a) of the Act]. An NDA must contain sufficient data to establish that the drug is both safe and effective for its intended use(s).

The tanning accelerators are misbranded [Section 502(f)(1) of the Act] in that their labeling fails to bear adequate directions for use. The tanning accelerators and sunscreen products listed above are misbranded [Section 502(o) of the Act] in that the drugs have not been listed as required by Section 510(j).

Letter to Mr. Christal

June 2, 1999

Page 2

The violations cited in this letter are not necessarily intended to constitute an all-inclusive statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that your drug products are in compliance with all requirements of federal laws and regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt measures to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

For your information, two of the sunscreen products you market under the tradenames "EMERALD BAY SPF 8" and "EMERALD BAY SPF 17" are labeled to contain "Butyl Methoxydibenzoylmethane (Parsol 1789)" as "other ingredients." Parsol 1789 is also known by the chemical name of avobenzone. The labeling for these products states they contain "Octyl Methoxycinnamate" and "Octyl Salicylate," as active ingredients.

A final rule in the form of a final monograph for over-the-counter sunscreen products was published in the Federal Register, Vol. 64, No. 98, on May 21, 1999. Avobenzone is included in this final rule as a sunscreen active ingredient. Companies marketing OTC drug products subject to this final rule have until May 21, 2001 to bring their products into compliance. Consequently, your company, under the final rule, should revise the labeling for the two subject products.

You should notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and time within which correction will be completed.

Your reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U.S. Food and Drug Administration
19900 Mac Arthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,



Thomas L. Sawyer
Acting District Director

Enclosures (2):

FR, Vol. 64, No. 98, June 1, 1999

FR, VOL. 62, No. 83 (pgs. 28293-28302), April 30, 1997

Letter to Mr. Christal

June 2, 1999

Page 3

Cc: Mr. Terry Katz
Senior Vice President
California Sun Care inc.
10877 Wilshire Blvd., 12th Floor
Los Angeles, CA 90024

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Food and Drug Branch
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