



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

August 4, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Alfredo Cortazar, President
Sombra Cosmetics, Inc.
5600-G McLeod NE
Albuquerque, New Mexico 87109

Ref. # - DEN-99-16

Dear Mr. Cortazar:

This letter is written in reference to the marketing of "SOMBRA Natural Pain Relieving Gel," also known as "Sore No More! Natural Pain Relieving Gel," by your firm. The product label states that the product contains the active ingredients "Menthol 3%, Camphor 3%, Capsaicin .03%." This product is also labeled to contain, as "other ingredients," Grapefruit Seed Extract, Green Tea Extract, Orange Peel Extract, Queen of the Prairie Extract, and Yucca Extract, among others. Because these "other ingredients" are featured prominently in the labeling and are intended to have a direct effect on the body of man, they are active ingredients as defined in Title 21, Code of Federal Regulations, Part 210.3 (b)(7).

The label on your product makes claims, including: "Natural Pain Relieving Gel... developed to treat aches, pain, swelling, inflammation, soreness of muscles and joints caused by sports injuries, stiffness, sprains and arthritis."

The brochures (labeling) which your firm distributes with this product also make numerous claims, including: "Sore No More! Natural Pain Relieving Gel ... relieve pain ... Get rid of pain the natural way ... This product works by having a topical anesthetic effect by depressing cutaneous sensory receptors... detoxifies tight sore joints, relieves arthritic pain, muscle soreness, inflammation and gives immediate relief of back pain ... Camphor ... Antiseptic and anesthetic ... Capsaicin ... relieves aches and pains of arthritis by intercepting the pain signals sent to the brain by inflamed joints ... Grapefruit Seed Extract ... anti-microbial ... Studies at Case Western Reserve University indicate that it may also prevent or cure certain skin cancers ... Orange Peel Extract ... anti-inflammatory ... Queen of the Prairie Extract ... high levels of salicylic acid, that works as an antiseptic... Yucca Extract ... anti-inflammatory and reduces erythema."

"SOMBRA" also known as (a.k.a.) "Sore No More" is a drug, as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended to be used in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or any function of the body of man.

"SOMBRA" (a.k.a.) "SORE NO MORE" is a "new drug", as defined in Section 201(p) of the Act, since we are not aware of any substantial scientific evidence which demonstrates that this drug is generally recognized as safe and effective for its intended uses. Accordingly, "SOMBRA" (a.k.a.) "Sore No More" may not be marketed in interstate commerce without approval of a New Drug Application as defined in Section 505 of the Act. Therefore, this drug is misbranded under Section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for the uses for which it is being offered.

This drug is also misbranded under Section 502(a) of the Act, in that its labeling is false and misleading because it suggests this drug is safe and effective for its intended uses, when this has not been established.

This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to assure that all requirements of the Act and regulations promulgated thereunder are being met.

We request that you reply within fifteen (15) days of your receipt of this letter stating the action you will take to discontinue the marketing of these drugs or otherwise bring them into compliance.

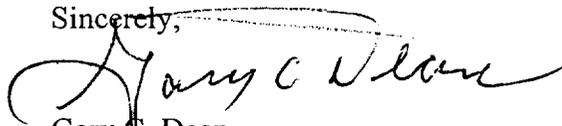
Your response should include (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which correction will be completed; (3) any reason why the corrective action has not been completed within the response time; and (4) any documentation necessary to show that correction has been achieved.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Food, Drug and Cosmetic Act provides for seizure of illegal products [Section 304] and for injunction [Section 302] against the manufacturer and/or distributor of illegal products. Federal agencies are advised of the issuance of all Warning Letters regarding drugs and devices so they may take this information into account when considering the award of contracts.

Your reply should be directed to the attention of Ms. Shelly L. Maifarth, Compliance Officer, Food and Drug Administration.

We have received your response of July 27, 1999 to our Warning Letter of July 14, 1999 regarding deviations to the Good Manufacturing requirements. We are granting the response deadline of August 30, 1999, as you requested.

Sincerely,



Gary C. Dean
Director, Denver District

**REVIEWED
NOTHING PURGED**