



DEPARTMENT OF HEALTH & HUMAN SERVICES

MTTler

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

July 14, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

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

Ref.: DEN-99-10

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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%." The ingredients also include Grapefruit Seed Extract, Green Tea Extract, Orange Peel Extract, Queen of the Prairie Extract, and Yucca Extract.

The label on your product makes therapeutic 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."

Your firm distributes brochures (labeling) with this product which 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 and fungicidal agent ... Green Tea Extract ... Used as an anti-irritant... mild antibacterial ... 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."

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These claims for "SOMBRA" also known as "Sore No More", found on the product label and brochure, establish that the product is a drug, (section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)) 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.

During our inspection of your manufacturing facility conducted between March 23 and 24, 1999, Consumer Safety Officer Barbara J. White documented deviations from the Good Manufacturing Practice (GMP) Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's operations. These deviations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Act. These deviations include:

1. Failure to test each batch of drug product for appropriate laboratory confirmation to final specifications for the drug product, including the identity and strength of each active ingredient, as required by Title 21, Code of Federal Regulations, Part 211.165(a) [21 CFR 211.165(a)]. The response your firm submitted to the FD-483, List of Observations, dated April 27, 1999, is inadequate. You submitted, after the fact, finished product testing for ~~the~~ active ingredients: ~~the~~. However, your drug product also contains several other active ingredients which have not been tested for in the finished product. 21 CFR 210.3(b)(7) defines an active ingredient as any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease. Grapefruit Seed Extract is an example of an active ingredient in your product which has not been tested in finished drug product. Your labeling describes Grapefruit Seed Extract as "An organic anti-microbial and fungicidal agent that is non corrosive and non irritant to the skin." As such, the extract is an example of an active ingredient, and requires appropriate finished product laboratory testing, including identity and strength tests.

2. Failure to withhold each lot of components from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by a quality control unit, as required by 21 CFR 211.84(a). Your response is inadequate because:

- The Certificate of Analysis (CoA) for the component ~~the~~ Lot # A974807 (released 1-26-99 by your firm) submitted with your response is not the same CoA as the original collected by our investigator during the inspection for the same lot # A974807 (released 1-26-99 by your firm). The one collected during our inspection is dated 21 Jan 99, and shows purity, color, and odor results. The one submitted with your written response has white-out on it, is dated 4/25/90, and shows purity, angular rotation, refractive index, specific gravity, solubility, heavy metals, and melting range test results. There should not be two completely different CoAs for the same lot of product.
- Component testing results submitted with your response, for active ingredients other than ~~the~~ USP, ~~the~~ USP, and ~~the~~, such as ~~the~~ and ~~the~~ is inadequate because it consists of determining color, odor, taste, texture, and viscosity or specific gravity. No identity or potency testing, for example, are performed.

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- There are no specifications established for the water used as a component. For example, there are no specifications for the quality of your water, the type and frequency of maintenance of your water system, and the reference standard of your water. Your response is not adequate, in that you submitted literature about the systems you use, but supplied no specifications as to what Sombra is actually producing and using as a component in their drug product.
3. Failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity, as required by 21 CFR 211.160(b). Your response is inadequate because the testing performed for active raw materials [X X X X X] and [X X] [X X X X X], is not adequate to assure that these components conform to appropriate standards of identity, strength, quality and purity.
4. Failure to validate your written procedures for production and process control to show that these procedures are designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 CFR 211.100(a). Your response is inadequate because it consists of only one validation run. This does not show your processes are repeatable. Also, you should have a validation protocol, which is a plan showing how you will complete your validation runs, and what you expect to find during these runs.
5. Failure to prepare, date, and sign master production and control records for your drug product, as required by 21 CFR 211.186(a). Your response is inadequate in that the records you submitted as master production and control records are not master records, but batch records describing the manufacture of a batch of product. Also, a review of the records submitted as master production and control records for lot numbers 21 and 44 do not have:
- A description of the drug product containers, closures, and packaging material, including a specimen or copy of each label and all other labeling signed and dated by the person responsible for approval of such labeling (21 CFR 211.186(b)(8)). Note that there are brochures which are part of the product labeling, and which are not included with the master record. There are also two names under which this product is marketed. There are specimens of the two sizes of "SOMBRA Natural Pain Relieving Gel," none of "Sore No More! Natural Pain Relieving Gel." Copies of product labeling for both products should be included in the master record.
 - Complete sampling and testing procedures and specifications, in that there are no instructions for sampling in-line or finished product, and the raw material specifications and testing procedures are inadequate (21 CFR 211.186(b)(9)).
 - The strength of the drug product (21 CFR 211.186(b)(1)).
6. Failure to adequately prepare batch production and control records for each batch of drug product produced which include complete information relating to the production and control of each batch, as required by 21 CFR 211.188. Your response is inadequate in that your records do not include:
- An accurate reproduction of the appropriate master production or control record (21 CFR 211.188(a)).

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- Laboratory control results (21 CFR 211.188(b)(5)).
- Inspection of the packaging and labeling area before and after use (21 CFR 211.188(b)(6)).
- Complete labeling control records, including specimens or copies of all labeling used (21 CFR 211.188(b)(8)).
- Description of the drug product containers and closures (21 CFR 211.188(b)(9)).
- Results of examinations made in accordance with 21 CFR 211.134 (drug product inspection) (21 CFR 211.188(b)(13)).

Please note that other records were reviewed and found to have the same deficiencies.

7. Failure to have an adequate written stability testing program designed to assess the stability characteristics of your drug products, as required by 21 CFR 211.166(a). Your response is inadequate in that your Standard Operating Procedure (SOP) entitled " [x x x x] [x x x x]" # [x x] issued 12/10/98 does not contain: sample size based on statistical criteria for each attribute examined to assure valid estimates of stability, as required by 21 CFR 211.166(a)(1), nor reliable, meaningful, and specific test methods, as required by 21 CFR 211.166(a)(3).

8. Failure to test an adequate number of batches of each drug product to determine an appropriate expiration date, as required by 21 CFR 211.166(b). Your response is inadequate because your stability testing data does not have lot numbers associated with the testing, nor any indication of the formula of the product being tested. It cannot be determined what exactly was tested for stability.

9. Failure to bear an expiration date determined by appropriate stability testing to assure that your drug product meets applicable standards of identity, strength, and purity at the time of use, as required by 21 CFR 211.137(a). For example, as noted above, your stability testing program and testing data are inadequate. Please note that you are not exempt under 21 CFR 211.137(h) in that you do not have appropriate stability data to support a 3-year expiration date.

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.

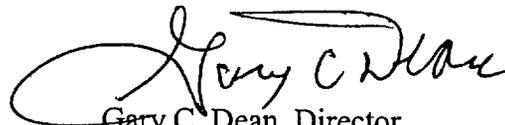
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Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Food, Drug and Cosmetic Act provides for seizure of illegal products (Section 304) and for injunction (Section 302) against the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

Please note that the drug status of your product (whether it is violative under the new drug provisions of the Act) is currently under review in the Center for Drug Evaluation and Research. As soon as their review is complete, we will issue a letter to you regarding our findings.

Your reply to the charges alleged in this letter should be directed to the attention of Ms. Shelly L. Maifarth, Compliance Officer, Food and Drug Administration. You may contact Ms. Maifarth with any questions you may have at (303) 236-3046.

Sincerely,



Gary C. Dean, Director
Denver District

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