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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone 303-236-3000
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October 21, 2002

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Leroy Harris
President
Zincomatic, Inc.
3026A 1/2 Road
Grand Junction, CO 81503

Ref: #-DEN-03-02

Dear Mr. Harris:

This letter concerns the manufacturing and marketing of "Exoderm Topical Skin Supplement" by your firm. During an inspection of your manufacturing facility on July 15 – July 17, 2002, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures, promotes, and distributes the product. The ingredients of Exoderm Topical Skin Supplement are declared as glycerin, zinc sulfate, and stannous fluoride.

In your signed affidavit, you state that your promotional material, "EXODERM Topical Skin Supplement", is distributed with the product to your customers. This brochure indicates that the product is offered as an effective aid in the treatment of conditions such as acne, boils, psoriasis, athlete's foot, cough, sinus problems, herpes, chicken pox, lupus lesions, and sores in the mouth due to chemotherapy. Based on the intended uses, Exoderm Topical Skin Supplement is a "drug" as defined in Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act) because it is intended to treat, cure, or prevent disease.

Exoderm Topical Skin Supplement is offered as treatment for the following conditions:

- acne, which is subject to the Final Rule for Topical Acne Drug Products for "over the counter" (OTC) Human Use under 21 CFR 333.310;

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- boils, which is subject to the Final Rule for Boil Drug Products for OTC Human Use under 21 CFR 310.531;
- psoriasis, which is subject to the Final Rule for Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for OTC Human Use under 21 CFR 358.710;
- athlete's foot, which is subject to the Final Rule for Antifungal Active Ingredient Drug Products for OTC Human Use under 21 CFR 333.210;
- cough, which is subject to the Final Rule for Antitussive Drug Products for OTC Human Use under 21 CFR 341.74; and
- sinus problems, which is subject to the Final Rule for Nasal Decongestant Drug Products for OTC Human Use under 21 CFR 341.80.

Exoderm Topical Skin Supplement is marketed in violation of the above final rules, and the product is not generally recognized as safe and effective for any of these claims. Therefore, this product is a "new drug" as defined in Section 201(p) of the Act and may not be legally marketed in the United States for these indications without an approved New Drug Application (NDA) under section 505(a) of the Act.

The Exoderm Topical Skin Supplement brochure also includes statements or suggestions that this product may be useful in the treatment of various diseases such as shingles, chicken pox, lupus lesions, herpes and sores in the mouth due to chemotherapy. We are unaware of any evidence which establishes that this drug is generally recognized as safe and effective for these intended uses. Therefore, this product is also a "new drug" as described in Section 201(p) of the Act and may not be legally marketed in the United States for these indications without an approved NDA under section 505(a) of the Act.

In addition, this drug is misbranded under Section 502(f)(1) of the Act because its labeling fails to bear adequate directions for use. See also 21 C.F.R. Part 201.

Finally, your product is also adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for its manufacturing, processing, packing, or holding do not conform or are not operated or administered in conformity with the Current Good Manufacturing Practice (CGMP) regulations to assure that your drug meets the requirements of the Act as specified in 21 C.F.R. Part 211. At the conclusion of the inspection, the investigator provided a list of these deficiencies on the form FDA 483, "List of Observations."

The above list of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you manufacture and distribute meet all of the requirements of the Act and its implementing regulations. Federal agencies are advised of issuance of all warning letters about drugs and devices

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so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the FDA without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of H. Tom Warwick, Compliance Officer, at the on the letterhead.

Sincerely,



B. Belinda Collins
Director, Denver District

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