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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

REGULATORY LETTER
90-DT-6

November 30, 1989

Mr. Robert S. Glancz
President
Mineral Cosmetics, Inc.
3824 West Twelve Mile Road
Berkley, Michigan 48072

Dear Mr. Glancz:

During the February 28 through March 1, 1989 inspection of your firm, our investigator documented that you are engaged in the manufacture and distribution of human drugs and cosmetics. Our investigation has revealed that your products are in serious violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) as follows:

Our review discloses that your labeling contains claims which represent and suggest that certain articles are intended to affect the structure and function of the human body such as, but not limited to, the following:

1. Collagen E Cream claims it "Strengthens the fragile capillaries".
2. Collagen-2000 claims it "prevents and retards aging".
3. Co-Elastin claims to "counteract the non-arresting physical decay".

Because of such claims, these products are drugs as defined in Section 201(g) of the Act. We are unaware of any substantial scientific evidence that demonstrates the safety and effectiveness of these articles for their intended uses, nor are we aware that these drugs are generally recognized as safe and effective for their intended uses. By virtue of the claims made, these articles are new drugs within the meaning of Section 201(p) of the Act.

Section	Brief Description
505(a) FD&C Act	Therefore, the aforesaid articles are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under

Section 505(a) of the Act since they are new drugs within the meaning of 201(p) of the Act, and no approval of applications filed pursuant to Section 505(b) are effective for such drugs.

502(f)(1) FD&C Act

The aforesaid articles are misbranded in that their labeling fails to bear adequate directions for use.

Additionally, "Facial Moisturizer with Sun Screen" is a drug within the meaning of Section 201(g)(1) of the Act and is misbranded in that the labeling fails to bear adequate directions for use, as required by 21 CFR 201.5, in that it bears no directions for use.

502(e) FD&C Act

"Facial Moisturizer with Sun Screen" is further misbranded in that it is also a cosmetic within the meaning of Section 201(i) of the Act and the label does not first declare the active drug ingredient(s) and then the cosmetic ingredients as required by 21 CFR 701.3(d) and further described in 21 CFR 201.10(a).

502(o) FD&C Act

You have failed to register with the agency as a drug manufacturer in accordance with Section 510 and to list your drugs with the agency in accordance with Section 510(j). The failure to register or list serves to misbrand all drug products manufactured by your firm.

501(a)(2)(B) FD&C Act

Drug products manufactured by your firm are adulterated in that the methods used in, or controls used for, the processing, packing or holding of drugs are not in conformance with Current Good Manufacturing Practice Regulations, Title 21 Code of Federal Regulations, Parts 210 and 211 [21 CFR Parts 210 and 211] including:

Failure to test each lot of component for conformity with all appropriate written specifications for purity, strength, and quality [21 CFR 211.84(d)(2)]. For example, active ingredient components are not tested for identity or strength. You may rely on a manufacturer's certificate of analysis, provided you conduct at least one specific identity test, and you establish the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Failure to assure that your drug products meet acceptable standards of identity, strength, quality, and purity at the time of use [21 CFR 211.137(a)]. Your OTC topical sunscreen lacks an expiration date, and there are no records of any stability testing to demonstrate stability for at least 3 years.

Failure to establish a written testing program designed to assess the stability characteristics of your drug products [21 CFR 211.166(a)].

Failure to incorporate the identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(b)].

502(b)(1) FD&C Act 1453(a)(1) FPLA — Various cosmetic products are misbranded in that they are in package form and the labels fail to bear the name and place of business of the manufacturer, packer or distributor in accordance with the requirements of 21 CFR 701.12. Products include, but are not limited to "Eye Cream", "Hand and Body Lotion","Peeling Cream", "Eye Contour Gel", etc.

1453(a)(1) FPLA — Several of the products in package form, offered for sale as consumer commodities, fail to bear an appropriate identity of the cosmetic in accordance with the requirements of 21 CFR 701.11 since terms such as "Creme Giovanni", "Co-Elastin Cream", Collagen E Cream", "Collagen 200 Cream" are neither common or usual names nor appropriately descriptive names for cosmetic products.

1453(a)(3)(A)(i) FPLA — Your cosmetic products are misbranded in that they are in package form and the labels fail to bear the net quantity of contents declaration in terms of U.S. weight or fluid measure (e.g. "NET WT - OZ", "NET CONTENTS ___ FL. OZ.") in accordance with the requirements of 21 CFR 701.13(b).

1454(c)(3)(B) FPLA — Your cosmetic products in package form are misbranded in that they are offered for sale as consumer commodities and the ingredient declarations that appear on the labels fail to list all ingredients in accordance with the nomenclature requirements of the

compendia listed in 21 CFR 701.3(c) (e.g., unacceptable terms such as "herbs", "germeben II", "arlacel 60", "cera flava", "white oil", "vitamin E", "FD&C Red", "FD&C Brown", "Mineral 2000", "Protosorb S-200", etc., appear in the ingredient declarations.

1454(c)(3)(B) FPLA — Several of your cosmetic products are further misbranded in that the ingredient declarations that appear on the product labels fail to appear with such prominence and conspicuousness as to render the declarations likely to be read and understood by ordinary individuals under normal conditions of purchase, in accordance with the requirements of 21 CFR 701.3(b), since the declarations appear on the bottoms of the containers (e.g., "Eye Cream", "Hand and Body Lotion", etc).

1454(c)(3)(B) FPLA — Your cosmetic product that is also a drug (i.e., "Facial Moisturizer with Sun Screen") is misbranded in that the ingredient declaration fails to first declare the active drug ingredient as required under Section 502(e) of the FD & C Act and then declare the cosmetic ingredients in accordance with the requirements of 21 CFR 701.3(d).

We request that you take prompt action to correct these violations. If prompt corrective action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions provided under the law. These include seizure and/or injunction.

This is not intended to be an all-inclusive list of violations which may be present at your firm. It is your responsibility to assure that you are in compliance with these laws and their enabling regulations.

Other areas of concern include:

-The label for "Facial Moisturizer with Sun Screen" and other drugs fail to bear a proper declaration of net quantity of contents in terms of U.S. gallons, or subdivisions thereof as required by 21 CFR 201.62(b). Declaring the net contents exclusively in metric is not permitted, but may be used in addition to the avoirdupois declaration per the cited regulation.

- Reference to vitamins and nourishment are inappropriate in the labeling of cosmetic products and may cause such products to be misbranded under section 602(a) of the FD&C Act since such references falsely convey the impression that the vitamins provide a nutritional or therapeutic benefit.

- When the name of a cosmetic, which contains two or more ingredients, includes the name of one or more ingredients, but not all ingredients, the name of the cosmetic may be misleading (See 21 CFR 701.1(b)) (For example: "Collagen Supreme Lotion", "Placenta Cleanser", "Co-Elastin Creme", etc).

- Comparison of product formulations with ingredient declarations on product labels reveal that the ingredient statements do not always list the actual ingredients in the product and do not always list them in descending order of predominance (For example: "Eye Wrinkle Cream" and "Placenta Cleanser").

We were unable to evaluate the appropriateness of the type size of the letters and numerals used in the quantity of contents declarations appearing on the principal display panels of the cosmetics offered for retail sale. The quantity of contents declarations on the principal display panels of the products must meet the appropriate height requirements of 21 CFR 701.13(i) and the placement of the net quantity of contents declaration must be in the lower 30% of the principal display panel, adequately separated from the printed material.

Also, we have conducted a limited review of your product labels, the product sheets contained in your "European Skin Care and Cosmetics, Inc." packet, and your "Mineral 2000" brochure. Our review discloses that your labeling contains claims which represent and suggest that some of your products are intended to affect the structure and function of the human body. Because of such claims, these products are drugs as defined in Section 201(g) of the Act.

- "GSL - Cellular Rejuvenating Cream". The name of this article represents and/or suggests that the product is useful for rejuvenating the skin, which is a drug claim.

- "Mineral 2000". Claims such as "restore the natural ionic balance and protective acid mantle of your skin", "supplies essential minerals", "prevents early wrinkles", "calm skin irritations" and "space-age answer to retaining a youthful skin" are drug claims.

- "Eye Cream" (reducing the swelling due to strain and tiredness), "Mineral Night Creme" (regeneration of cells), "Sulpher Cream" (regulation of the sebaceous glands), "Astringent" (shrinks enlarged pores), "Camphor Cleanser" (bacteriocidal activity), "Camphor Toner" (increased activity when treating oily, blemished skin), "Drying Lotion" (eliminates blemishes), "Astringent Mask" (antiseptic), "Oatmeal Mask" (Excellent for blackheads and skin dandruff problems), "Herbal Protein

Mask" (revitalize and nourish tired skin), "Lecithin-Honey Mask" (influences penetration of tissue, nourishes skin), "Avocado Mask" (nourishing, helps prevent premature skin surface flaking), "Collagen Mask" (nourishes, revitalizes), "Mineral 2000 Facial Spray" (supplies essential minerals, maintains the ionic balance and acid protection of the skin).

Additionally a sample of the deionized water which you use in the production of various products was collected and analyzed during our inspection. Analysis found aerobic plate counts (APC) of 91,000 organisms per gram in subsample 1 and 65,000 organisms per gram in subsample 2. Subsample 1 contained the following organisms: Staphylococcus epidermidis, Alcaligenes denitrificans, Alcaligenes odorans, and Pseudomonas pickettii. Subsample 2 contained the following organisms: Staphylococcus epidermidis and Flavobacterium odoratum. We are concerned by the presence of these organisms in water used for production and request that you take appropriate action to assure the microbial quality of such water. A copy of our analytical results is attached.

Please notify us in writing, within ten (10) days of your receipt of this letter, of the specific steps you have taken, or intend to take, to correct these violations and to prevent their recurrence. If corrective action cannot be completed within ten days, please provide the reason for the delay, and the time within which the corrections will be completed.

Your response should be sent to this office to the attention of Sandra Williams, Compliance Officer.

Sincerely yours,

Carl C. Reynolds
District Director
Detroit District

Encl: a/s