DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

REGULATORY LETTER
91-DT-17

March 21, 1991

Eugene F. McKay, President
Marlo Manufacturing Corp.
1415 Read St.
Evansville, IN 47710

Dear Mr. McKay:

During the October 17 through 22, 1990 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:

Princess Nyla Youth-Lift - the product hand-out contains the claims, "Working down to the fifth (muscle) layer of the skin, "Youth-Lift" can and does exercise the facial muscles. *** Youth Lift works as a passive, involuntary muscle exercise, *** Toning and firming the muscle layer means a firmer, fuller layer, and in turn fills out the upper layers so they are firmer and many lines less apparent (sic) or seemingly disappear altogether."

Because of such claims, this product is a drug as defined in Section 201(g) of the FD&C Act. We are unaware of any substantial scientific evidence that demonstrates the safety and effectiveness of this article for its intended use, nor are we aware that this drug is generally recognized as safe and effective for its intended use. By virtue of the claims made, this article is a new drug within the meaning of Section 201(p) of the FD&C Act.

SECTION	BRIEF DESCRIPTION
505(a) FD&C Act	Therefore, the aforesaid article is a drug 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 it is a new drug within the meaning of 201(p) of the Act, and no approval of an application filed pursuant to Section 505(b) is effective for such drug.
502(f)(1) FD&C Act	The aforesaid article is misbranded in that its labeling fails to bear adequate directions for use.
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.
602(b)(1) FD&C Act 1453(a)(1) FPLA	Your cosmetic products are misbranded in that they are in package form and the labels fail to bear the actual name and place of business of the manufacturer, packer or distributor in accordance with the requirements of 21 CFR 701.12, since Nyla Laboratories, which is not the corporate name, is the name of business listed on the label. In the case of corporations, the requirement for declaration of the name of the manufacturer, packer or distributor on the label is satisfied only by the actual corporate name [21 CFR 701.12(b)]. In addition, the place of business on the product labels lists an incorrect Zip Code.
602(a) 201(n) FD&C Act	Your Bubbling Bath Oil products are misbranded in that they are foaming detergent bath products as that term is defined at 21 CFR 740.17 and the label fails to reveal material facts in that it does not bear the specific warning statement required under 21 CFR 740.17(b).
1453(a)(1) FPLA	Several cosmetic 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 "Medlo Special Formula" and "Teen Clean" are neither common or usual names, nor appropriately descriptive names, for cosmetic products.

1453(a)(2) FPLA	Your cosmetic products are misbranded in that they are in package form and the labels fail to bear the declaration of net quantity of contents on the principal display panel of the label (as that term is defined at 21 CFR 701.10), as required by 21 CFR 701.13(e) and (f).
1454(c)(3)(B) FPLA	Your cosmetic products in package form (e.g. Dry Skin Night Cream, Bouquet Bubbling Bath Oil, etc.) are misbranded in that they are offered for sale as consumer commodities and the label on each package fails to bear a declaration of ingredients, in accordance with the requirements of 21 CFR 701.3.

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. We have enclosed a copy of the FDA Cosmetic Handbook for your reference and use.

We note that our June 29, 1978 Notice of Adverse Findings letter stated that it is acceptable for your firm to provide a list of ingredients with each product on a separate sheet of paper. This interpretation of 21 CFR 701.3(i) was incorrect and you should not rely upon it, in that many of your containers have a total surface area of greater than 12 square inches, and the specific requirements of 21 CFR 701.3(i)(1) or (i)(2) must be met if separate sheets are used. (Please refer to the FDA Cosmetic Handbook for the complete text of this regulation).

We have the following additional comments:

- Reference to vitamins is 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.

- The net quantity of contents declaration appearing on the labels of some of your cosmetic products fail to appear in letters and numerals in a type size established in relationship to the area of the principal display panel of the package. For example, the type size of the letters and numerals in the net quantity of contents declaration on the label of the 4 ounce size of "Dry Skin Night Cream" is smaller than the one-eighth of an inch in height required by 21 CFR 701.13(i)(2).

- The identity statements appearing on the principal display panels of your cosmetics offered for sale as consumer commodities generally fail to appear in a size that is reasonably related to the most prominent printed matter on such panel in accordance with the requirements of 21 CFR 701.11(c).

- Several of the ingredients listed on the Ingredient Statement sheets are not declared in accordance with the ingredient nomenclature requirements of 21 CFR 701.3(c). For example, the correct ingredient nomenclature for "zinc sulphate", "Vitamin A palmitate", "Vitamin D" and "nonoxynon-10" is "zinc sulfate" retinyl palmitate", "ergocalciferol" and "nonoxynol-10", respectively. You should assure yourself that all ingredients are properly declared on the product labels in accordance with the nomenclature requirements of 21 CFR 701.3(c).

- Review of Ingredient Statement sheets dated 6/1/89 reveals that FD&C Red #3 is listed as being a color additive used in products which include "Bouquet Bubbling Bath Oil" and "Delicate Skin Night Cream". The use of this color is prohibited from being added to cosmetic products formulated and manufactured after January 29, 1990 and would cause such products to be deemed adulterated under Section 601(e) of the Federal Food, Drug and Cosmetic Act.

- The term "Anti-aging appearance" in reference to GSL Concentrate Cream is not appropriate for a cosmetic product and should be deleted from your labeling.

- The claim that Dry Skin Night cream topically replaces vitamins and minerals is not appropriate for a cosmetic product and should be deleted from your labeling.

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 frame within which the corrections will be completed.

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

Sincerely yours,

John A. Dempster
for Carl C. Reynolds
District Director
Detroit District

Encl.: a/s