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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL- RETURN RECEIPT REQUESTED

REGULATORY LETTER

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2
Telephone (213) 252-7583

June 13, 1990

LA-27-0

Ember J. Safford, President
Dutch Pride Products, Inc.
1287 Rainbow Drive
Cottonwood, Arizona 86326

Dear Ms. Safford:

This letter is written in reference to the marketing of BIO-"10" by your firm.

Promotional material (labeling) distributed with your product states or suggests that it is useful for, among other conditions, bacterial, fungal and viral infections; herpes; Candida albicans; carcinoma of the scalp; enhancement of the immune system; shingles; kidney, bladder and prostate infections.

Because such labeling includes statements which represent and suggest that this article is intended to be used in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body of man, this product is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Further, we are unaware of any substantial scientific evidence which demonstrates that this drug is generally recognized as safe and effective for any of the aforementioned conditions. Accordingly, marketing of this drug is a violation of the Act as follows:

SECTION	BRIEF DESCRIPTION
502(a)	The article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the article is safe and effective for the prevention or treatment of the conditions indentified above.
502(f)(1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for use for the conditions for which the article is represented or suggested, and it is not exempt from this requirement under Regulation 21 CFR 201.115 since the article is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for this drug.

	The article of drug is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5, since the conditions for which it is offered are not amenable to self diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use this drug safely and for the purposes for which it is intended.
505)a)	The article is a drug within the meaing 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 Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drug.

We also consider BIO-"10" to be in further violation of the food misbranding provisions of the Act as follows:

SECTION	BRIEF DESCRIPTION
403(a)(1) 21 CFR 101.9(i)(1).	BIO-"10" offered as a dietary supplement is misbranded in that it is falsely represented as adequate or effective to affect the structure or function of the body for the labeled conditions such as: "... enhances the body's efficiency by adding oxidation potential, since the action occurs at a fundamental cellular level." Additionally, promotional material (labeling) distribution by your firm for BIO-"10" states or suggests that the product "... may act as a supplement to the body's immune system by adding oxidation potential ... may assist the body to fight a variety of infectious agents ... known to release simple mineral agents that appear to be active against bacteria and fungi, as well as a number of viruses such as herpes."
403(i)(1) 21 CFR 101.3, 102.5	The BIO-"10" label lacks appropriately descriptive terms of the basic nature of this food or its characterizing properties or ingredients as statements of identity in that the label states that the product is "purified water containing mineral oxides."

The above enumeration of deficiencies should not be construed as an all inclusive list of violations which may be in existence with your products. It is your responsibility to ensure that all requirements of the Act and the regulations promulgated thereunder are being met.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should include:

1. An estimate of the quantity of BIO -"10" manufactured or received within the past twelve (12) months.

2. An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3. An estimate of the amount of the product that is in inventory under your control and your estimate of the amount in distribution channels outside your control.

4. The date of discontinuance in the event that you have already discontinued marketing this product.

5. Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to :

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 W. Pico Blvd
Los Angeles, CA 90015

Sincerely,

George D. Gerstenberg
District Director

[redacted]