



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

g3862d

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
FAX: 303-236-3100

August 8, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Jau-Fei Chen
President
E. Excel International, Inc.
1198 North Spring Creek Place
Springville, Utah 84663

REF #: DEN-00-30

Dear Dr. Chen:

This letter is written in reference to the marketing of various products by your firm. These products are marketed and promoted through several types of media including your magazine, "The Excellent Word." This magazine is labeling and includes statements or suggestions that several products, identified below, may be useful for treating various diseases. Disease claims in "The Excellent Word" cause these products to be drugs. Additionally, several products that your firm markets as foods are discussed in this letter.

Products that are drugs and their associated disease claims are:

Millennium Fine Cactus Nectar: fighting tumor growth, Epstein Barr Virus, treatment of diabetes.

Duet Ginseng & Cactus Nectar: cytotoxic activity against leukemia cells, anticonvulsant, antipyretic, antipsychotic, ulcer protection, Alzheimer's disease, cardiovascular disease, cerebrovascular disease, central nervous system diseases, liver disease, and blood and hematopoietic system diseases.

Vision, Noco, Daily Nutrition Pack: reduced immune function, inflammation, degenerative diseases such as arthritis.

PURGED

Page 2 – Warning Letter
August 7, 2000

Nutrifresh and Nutriall: osteoporosis, lower cholesterol and therefore reduce the risk of heart disease, anticarcinogenic, cancer, discourages the growth of breast, colon, lung, leukemia, and prostate cancer cells.

Because your labeling includes statements which represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease, these products are drugs under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

We are unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are new drugs as described in Section 201(p) of the Act which may not be marketed since no new drug application required by Section 505 of the Act has been approved for any of these drugs.

These drugs are also misbranded under Section 502(a) of the Act because their labeling is false and misleading since it suggests that these drugs are safe and effective for their intended uses, when, in fact, this has not been established. These drugs are further misbranded under Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for their intended uses.

As I have stated, the above products (Millennium Fine Cactus Nectar, Duet Ginseng & Cactus Nectar, Vision, Noco, Daily Nutrition Pack, Nutrifresh, and Nutriall) are drugs as currently labeled. If the drug claims for these products are eliminated, the products then become dietary supplements or foods along with the remaining products cited in this letter. The following deficiencies apply, and should be corrected:

Your Nutrifresh product (Original, Peach, Chocolate, Strawberry, and Mixed Fruit) is misbranded under Section 403(r)(1)(A) of the Act, in that its label may not contain nutrient content claims that are not authorized for use. For example, this product bears the unauthorized nutrient content claim “Rich in Phytonutrients,” for which there is no established daily value.

Your products Nutriall Health Drink, Nutrifresh, Refresh, Triflora, and EverNew are misbranded under Section 403(i)(1) of the Act in that the labels fail to bear a statement of identity by common or usual name or an appropriately descriptive term, as required by Title 21, Code of Federal Regulations, Part 101.3(b) [21 CFR 101.3(b).] The products are dry powders, and should include a term such as “mix” to describe the nature of the products. Millennium Fine Cactus Nectar and Duet Ginseng & Cactus Nectar are also misbranded under Section 403(i)(1) of the Act in that their labels fail to bear a statement of identity by common or usual name, or an appropriately descriptive term, as required by 21 CFR 101.3(b).

Your products labeled as dietary supplements are misbranded under Sections 403(q)(5)(F) and 403(s)(2)(A) of the Act, in that their labels do not list in the supplement facts box the identity and quantity of each dietary ingredient used in the products, as required by 21 CFR 101.36. Your products ST, Concenergy, Dong-Quai, Circle, Art, Act, Pearl, Vision, Ji-Lin Ginseng, DI,

PURGED

Noco, and WL identify one or more herbal dietary ingredients in the ingredient statement, but do not list the identity and quantity of each dietary ingredient in the supplement facts box.

Your products which contain botanical or herbal dietary ingredients or extracts of an herb or botanical are misbranded under Section 403(s)(2)(C) of the Act, in that their labels do not identify the part of the plant from which the dietary ingredients are derived, as required by 21 CFR 101.36. For example, your products ST, Concenergy, Dong-Quai, Circle, Art, Act, Pearl, Vision, Ji-Lin Ginseng, DI, Noco, and WL are labeled as containing botanical or herbal dietary ingredients or extracts of an herb, but the product labels do not identify the part of the plant as required by the regulation.

Your product Noco is misbranded under section 403(i) of the Act, in that the label must list the each herb or botanical ingredient by its common or usual name, as required by 21 CFR 101.4(h). The ingredient statement on the label for Noco does not list the common or usual name for the ingredient “Jin-Jie.”

Your products Millennium Fine Cactus Nectar and Duet Ginseng & Cactus Nectar are misbranded under Section 403(i)(2) of the Act, in that the products are fabricated from two or more ingredients and the label on the outside container does not bear the common or usual name of each ingredient. The ingredients are either missing or are not easily read by ordinary individuals under customary conditions of purchase and use.

Your product, Stevia, is labeled with directions for use that include the statement “dietary supplement.”

- a. If this product is intended to be a dietary supplement, 21 CFR 101.3(g) requires that the label bear the statement “dietary supplement”, or alternatively, “Stevia Supplement,” as part of the identity statement. In addition, 21 CFR 101.36(e) requires that the label contain “Supplement Facts.”
- b. If this product is not intended to be a dietary supplement, but a conventional food, 21 CFR Part 170 requires that the product be generally recognized as safe for its intended use, or used in accordance with the provisions of an authorizing regulation under 21 CFR Part 171, which describes safe use conditions. In addition, regulations require that appropriate Nutrition Facts information be included on the labeling.
- c. If this product is intended to be a cosmetic as defined in Section 201(i) of the Act, then appropriate regulations for cosmetics should be followed.

The vignette on the labels of your Nutrifresh (Original, Peach, Chocolate, Strawberry, and Mixed Fruit) products depicts a variety of fruits, some of which are not ingredients in each of these products. The vignettes should be changed so they show only those fruits that are actually found in each product.

PURGED

Page 4 – Warning Letter
August 7, 2000

We request that you notify this office in writing within 15 days of receipt of this letter stating the action you will take to discontinue the marketing of these products or to otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all of the products distributed by your firm. It also does not represent a complete review of all product labeling or promotional materials, including any Internet web sites, you may use. As the president, it is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

Your reply should be directed to the attention of Mrs. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,



Thomas A. Allison
District Director

PURGED