



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

July 11, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 26

Daniel E. Schroeder
President
Edan Naturals, LLC
248 Chicago Road
Wautoma, Wisconsin 54982

Dear Mr. Schroeder:

This letter is in reference to your firm's manufacturing and labeling of various products documented by our inspections conducted on January 23, April 14 and 18, 2003, at your facility located at 248 Chicago Road, Wautoma, Wisconsin. These inspections were conducted to determine your firm's compliance with the Federal Food, Drug and Cosmetic Act (the Act) and applicable implementing regulations contained within Title 21 of the Code of Federal Regulations (CFR).

We understand that you manufacture the seven products listed below for  and that these products are labeled under the brand name .

-  (non-dairy powder)
-  (capsules)
-  (non-dairy powder)
-  (capsules)
-  (capsules)
-  (capsules)
-  (powder)

Our review of the labeling of these products found several violations of the Act. First, these products are misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition labeling as required by 21 CFR 101.9 and the products are not exempt from this requirement under section 403(q)(5) of the Act.

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More specifically, the ingredient fructooligosaccharide belongs to a class of carbohydrates and must be declared as such in the nutrition labeling as required under 21 CFR 101.9(c)(6). Furthermore, the nutrition information on the label of your products fails to include all the nutrients required by 21 CFR 101.9(c). At a minimum, the following nutrients must be declared in the nutrition labeling ("Nutrition Facts") panel: total calories, total fat, total carbohydrates, protein, and sodium.

Next, these products are misbranded within the meaning of section 403(i)(2) of the Act and 21 CFR 101.4 because the ingredient statement does not declare the microbial ingredients. Instead, the microbial ingredients are incorrectly placed inside the nutrition facts panel.

Finally, the products labeled [redacted] (non-dairy powder), [redacted] (capsules), [redacted] (non-dairy powder), and [redacted] (capsules) are misbranded within the meaning of section 403(i)(1) of the Act and 21 CFR 101.3(b). The principal display panel must show the common or usual name of a food, which may be a coined term, and which must accurately identify or describe, in as simple and direct terms as possible, the basic nature or characterizing properties of the food or ingredients. The principles to be used in meeting this requirement are set forth in 21 CFR 102.5. The use of the acronym [redacted] does not meet the requirement, as the term does not describe the basic nature or characterizing properties of the food.

This letter is not intended to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that all products manufactured and labeled by your firm are in compliance with the Act and its implementing regulations. FDA regulations are available on FDA's website at www.fda.gov.

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

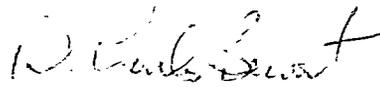
Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective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

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Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

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