



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 24 2000 0201 '00 DEC -7 P3:07

Ms. Michele Opheim
Sales Director
Nordic Naturals
3040 Valencia Avenue, #2
Aptos, California 95003

Dear Ms. Opheim:

This is in response to your submission to the Food and Drug Administration (FDA), received on November 17, 2000. Your submission appears to be intended to be the notification required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not state that you, as the responsible official, are certifying that the firm is in compliance with the requirements of the Act and the regulation. Therefore, you have not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit a notification in accordance with the requirements in 21 CFR 101.93(a).

Nonetheless, we have reviewed the information you submitted and have the following comment on the claims for the product named "Detoxification Formula." The product is claimed to be "an ideal therapeutic agent for methylmercury [sic] poisoning" and to contain an ingredient "that has been the subject of research for preventing methylmercury poisoning." The statements for this product, as well as the use in labeling of literature references describing the use of ingredients to treat methylmercury poisoning, suggest that it is intended to treat, prevent, or cure for methylmercury poisoning.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this products suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug

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Ultimate Detox line:

Product name: Detoxification Formula

SF: Supports Heavy Metal Removal

Ingredients:

Alginate : a proven heavy metal binder that immobilizes toxins in the digestive track and removes them from the body

N-Acetylcysteine (NAC): An amino acid that stimulate glutathione synthesis, promotes detoxification, enhances elimination of heavy metals

MSM™(methylsulfonylmethane): Sulfur donor

Vitamin C: Added antioxidant, synergistic support for NAC

Selenium: Powerful antioxidant

Zinc: Immune system support

General Nutrient Support: Alginate, from phaeophyta algae, has been shown to be beneficial in the binding and removal of some heavy metals, thus aiding in the prevention of their toxic burden on the body. Phaeophyta, or "brown algae" work through ion exchange, forming indigestible, insoluble salts that are excreted from the body. (Tanaka, et al.). NAC or N-Acetylcysteine is a sulfur amino acid that has been the subject of research for preventing methylmercury poisoning. NAC has shown ability to enhance methylmercury excretion, has relatively low toxicity, and maybe an ideal therapeutic agent for methlmercury poisoning (Ballatori, et al).

Selenium and vitamin C are known antioxidants, and help to support the detoxification process. Ascorbic acid (vit C) has also shown to be associated with reduced blood levels of lead in both young children and adults, reported. Dr. Joel A. Simon and Dr. Esther Hudes, both at the University of California at San Francisco. Their findings in the May issue of the Journal of the American Medical Association (JAMA).

References:

Tanaka, et al. Application of Algal Polysaccharides as in vivo Binders of Metal Pollutants, Gastrointestinal Research Laboratory, McGill University, Montreal, Canada & the US EPA

Ballatori, et al Environmental Health Perspectives Vol. 106, Number 5, May 1998

NORDIC NATURALS

*The Ocean Product
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