DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

JUL 15 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Sea-Biotics Inc.
525 W. Arapaho Road, # 14
Richardson, Texas 75080

Dear Sir:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.seabiotics.com/retail/products.asp and has determined that the products Alkyl Transfactor™ and Childrens' Neurofactor™ are promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some claims observed on your web site include:

- "Cell mis-communication causes our bodies to receive the wrong signals which causes cell membrane dysfunction. This cell membrane dysfunction is a critical factor in the develoment of virtually every chronic disease, especially cancer, diabetes, arthritis and heart disease.

  Our solution to cellular mis-communication is Alkyl-Transfactor™ and Childrens' Neurofactor™. The nutrients found in Seabiotics proprietary formulas have shown tremendous protective effects against all of these diseases. Scientific studies from around the world show that EPA and DHA [components of Alkyl-Transfactor™ and Childrens' Neurofactor™]... help[] to prevent and control serious health disorders, including heart disease, cancerous tumors, and numerous auto-immune and inflammatory diseases."

- "Fish Oil [an ingredient in Alkyl-Transfactor™ and Childrens' Neurofactor™] Does Treat Cancer ...."

- "Autism, Dyslexia, ADHD & some depression problems and how fish oils can change the picture for certain people ...

  - [P]ossible treatment to fight some of the symptoms of autism.... [F]ish oils may relieve some of the behavioral issues Autistic children display....

  - [R]ecommendation that Autistic children be supplemented with: Eicosapentaenoic Acid (EPA) Gamma Linoleic Acid (GLA) Vitamin E
    - 'In children taking supplements daily, parents have reported less aggression, hyperactivity and improvements in sleep disturbance, which can be a major problem in autism. In some instances, there have been improvements in speech and basic behavior as well as the ability of the child to concentrate and attend what is going on.' says Dr. David Bell ....
  - These two fatty acids [DHA and EPA] are pivotal in preventing heart disease, cancer, and many other diseases.... [L]ow DHA levels have been linked to depression, schizophrenia, ... and a higher risk of developing Alzheimer's."

- "How Fish Oil Can Treat & Prevent Cancer ...
  - Long-chain EPA and DHA, which are polyunsaturated omega-3 fats contained primarily in fatty fish, have been shown consistently to inhibit the proliferation of breast and prostate cancer cell lines in the test tube and to reduce the risk and progression of these tumors in animal experiments."

- "How Fish Oil Prevents Cancer ...
  - DHA also has been shown to improve the response of breast tumors to cytotoxic agents."

- "Intake of fish oils also has been observed to inhibit the metastasis of human breast cancer cell lines growing as solid tumors in animal models."

Furthermore, the conditions for which Sea-Biotics Alkyl-Transfactor™ and Childrens' Neurofactor™ are offered are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these drugs safely for their intended purposes. Thus, Sea-Biotics Alkyl-Transfactor™ and Childrens' Neurofactor™ are misbranded under section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use (21 U.S.C. § 352(f)(1)).

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling,

catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be drugs.

Certain over-the-counter drugs may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 CFR) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Kristen Moe, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Judith A. Gushee
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition