



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7520 Standish Place-Room 254
Rockville, MD 20855

April 9, 2001

Ref. No. 01-HFD-310I-105

Mr. Peter Karpinski
Batory A. M., Inc.
21 Port Meadow Trail
P.O. Box 396
Fairport, NY 14450

Dear Mr. Karpinski:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.internetauctioneer.com> and has determined that the products, "DHEA", "Ginkgo Biloba" and "St. John's Wort" being offered are promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)]. The products may be considered drugs because the therapeutic claims as shown on your web site establish their intended use as drugs.

Examples of some of the claims observed on your web site include the following, in part:

DHEA "...the most common hormone in the human body...it reduces...strokes or heart attacks...helpful in certain types of cancers, Alzheimer's disease, multiple sclerosis, memory loss prevention, chronic fatigue syndrome, and Parkinson's disease"

Ginko Biloba "...Improve Dementia...depression, dizziness, ringing in the ears, headaches, and senile macular degeneration (a major cause of blindness)...Parkinson's and Alzheimer's disease."

St. Johns Wort "... used in Europe as an antidepressant...Nature's Prozac...Because federal law bars companies from making health claims about dietary supplements, St. John's wort packages make no mention of depression or weight loss."

Furthermore, FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, they may also be ~~new drugs~~ under section 201 (p) of the Act [21 USC 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505 (a) of the Act [21USC 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

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 or as cosmetics if certain therapeutic claims 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 (DSHEA), dietary supplements may be legally marketed with claims that they are intended to affect the structure or function of the body (structure/function claims) if certain conditions are met. Claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims) excepting health claims authorized for use by FDA, may not be made as they 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 statements allowed as structure/function claims and those that represent disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>. In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter into the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, disease or structure/function claims may cause them to be new drugs.

Additional information is available in Title 21, Code of Federal Regulations, (21 CFR) Parts 310 and 330-358. These parts include the Final Rules for various OTC ingredients or products that may or may not be legally marketed without prior approval.

In addition, it has been brought to our attention by Le Chef du De'partement de la Publicit'e Et du Bon Usage des Produits de Sant'e (France), that the marketing of your products to citizens of France, without permission from the Agency for the Security of Health Products, is prohibited. Under the Act, a drug product that cannot be legally sold in the United States because it is unapproved, adulterated, and/or misbranded may be exported only if it meets the requirements of an applicable export exemption. Your product does not qualify for export to Australia because section 802(b)(1)(A) of the Act requires, among other things, that the unapproved drug to be exported must comply with the laws of the importing country. Exports of unapproved drugs under section 802(b)(1)(A) must also comply with section 801(e)(1)(B) of the Act, which conditions export on the product not being in conflict with the laws of the country to which it is intended for export. Because your products appear not to comply with the laws of France and is in conflict with those laws, it may be considered unapproved, adulterated, and/or misbranded under the Act, and may not be exported.

This letter is not intended to be an all-inclusive review of your web site and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 reach FDA electronically (E-mail) at Leggett@CDER.FDA.GOV or you may respond in writing to Don Leggett, Food and Drug Administration, HFD-300, 7520 Standish Place, Rockville, MD 20855 or by telephone at (301) 594-0054.

Sincerely yours,

/s/

David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

