DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 14, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John D. Seleen, President
JHS Natural Products, LLC
P.O. Box 50398
Eugene, Oregon 97405

Ref. No. CL-06-HFS-810-231

Dear Mr. Seleen:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.mushroomscience.com and has determined that the products "Coriolus-PSP" and "Coriolus VPS" are promoted for conditions that cause the products to be drugs 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 products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Coriolus-PSP

- "PSP is used to stimulate immune function and to support immune health, both before and/or after surgical treatment for cancer, and to support immune health during conventional cancer treatment."

Coriolus VPS [also referred to on your web site as VPS® Coriolus]

- "In traditional herbalism hot water extracts of Coriolus were used to … treat pulmonary infections …."
- "[I]t was … success in using Coriolus for stomach cancer that … subsequently launched the research and development of what came to be known as PSK" [your web site states elsewhere that the hot water extract of Coriolus is "[k]nown as … PSK in Japan" and describes your product Coriolus VPS as a "PSK/Japanese Formula"]
- "At this point the Coriolus extract was being prescribed by a significant percent of Japanese M.D.'s. Coriolus polysaccharides were used … to support and protect immune health in those patients receiving therapies where immune suppression is a prominent feature."

- "In one particular study Coriolus polysaccharides were given to … patients with gastric cancer, and the polysaccharides stimulated a significant immune response within 24 hours."
- "Recent U.S. research has confirmed [that] … these [Coriolus] polysaccharides … acted as a potent inducer of … tumor cytotoxicity … in in vitro studies."
- "The use of Coriolus polysaccharides to support immune health was studied in a randomized, controlled, clinical trial after curative surgery for colon cancer. The follow up time was ten years. The researchers found that, when compared with the control group (surgery only), the leukocyte activity of the Coriolus group showed 'remarkable enhancement'." (quoting study published in Cancer Immunology Immunotherapy)
- "Coriolus polysaccharides have also been studied for their immuno-restorative effect in those people receiving radiation treatment after surgery for non-small cell lung cancer. This study found that the 'five-year survival rate of the patients (who received Coriolus polysaccharides) with stages I or II disease, as well as stage III, was 39% and 22% respectively, compared with the non-administered groups' 16% and 5%. These differences are statistically significant.' Stage III patients that received Coriolus polysaccharides along with radiation had a better survival rate than stage I patients receiving radiation alone (22% vs. 16%)." (quoting study published in Anticancer Research)

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 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 [21 U.S.C. § 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 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 truthful and non-misleading 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 new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) 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 me at the Food and Drug Administration, 22201 23rd Drive S.E., Bothell, Washington 98021-4421. If you have any questions concerning this letter, please contact me at 425-483-4940.

Sincerely yours,

/s/

Lisa M. Althar
Compliance Officer