



Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Federal Express

WARNING LETTER

April 6, 2010

Ms. Megan Powers, President

Aloha Medicinals, Inc.
1135 Makawao Avenue, #314
Makawao, HI 96768

Dear Ms. Powers:

This letter concerns your firm's marketing of "Immune-Assist," "Levolar Forte," "Agaricus blazei Murill," "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune." Based on statements made on your website at the Internet address www.alohamedicinals.com, these products are drugs under section 201 (g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321 (g)(1)(B)] because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals. Further, "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are drugs under section 201 (g)(1)(C) of the Act [21 U.S.C. § 321 (g)(1)(C)] because they are intended to affect the structure or function of the body of animals. Additionally, "Immune-Assist," "Levolar Forte" and "Agaricus blazei Murill" are new drugs under section 201 (P) of the Act [21 U.S.C. § 321(p)], and "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are new animal drugs under section 201(v) of the Act [21 U.S.C. § 321(v)], because they are not generally recognized, by qualified experts, as safe and effective for their labeled uses.

Some examples of statements on your website that establish these intended uses for your products include, but are not limited to, the following:

Immune-Assist

- "Immune System Dysfunction Is The Greatest Threat To Americas [sic] Health Today! Diseases such as Cancer, Hepatitis, and Lyme disease are at least partially caused by our immune systems [sic] inability to correctly identify and destroy the aberant [sic] cells and invaders. Now you can do something about it! Immune-Assist™ Critical Care Formula is the most effective immune system enhancer yet developed!"

In addition, when reports of scientific studies are used commercially by the seller of a product to promote the product to consumers, such study reports may become evidence of the product's intended use. For example, under 21 CFR 101.93(g)(2)(iv)(C), a citation of a publication or reference in the labeling of a dietary supplement is considered to be a claim about disease treatment or prevention if the citation refers to a disease use and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease. Under the heading, "More Information about Immune Assist," you list paraphrased versions of the titles of several scientific articles and link to the corresponding articles, posted elsewhere on your website. Both the paraphrased titles and the scientific articles are accompanied by "Order Now" links to another page on your website where consumers can buy your products, including Immune-Assist. Both the paraphrased titles and the scientific articles posted on your website evidence intended uses of your Immune Assist product. The following are examples of descriptive links to scientific articles used to market your Immune Assist product for disease treatment and prevention on your website:

- "Reducing the side effects: Using Immune Assist in Cancer treatment to reduce side effects: Cancer Clinical Trial"
- "Immune Assist as adjunct for Eпивir (Lamivudine) in Hepatitis: Hepatitis Trial"
- "Immune-Assist as an Adjunct for Chemo-and Radiation treatment in Cancer patients"
- "Immune-Assist for Alcoholic Liver Disease and Hyperlipidemia"
- "Immune-Assist along with Eпивir for Hepatitis B"

Levolar Forte

- "Metabolic syndrome or Syndrome X is a cluster of diabetes-like symptoms that has reached epidemic proportions in our western society. It is characterized by fatigue, high cholesterol, high blood sugar, kidney disease, hardening of the arteries and other health challenges, causing our high hopes and good intentions for living the good life to be cut short. Heart disease and stroke are 2-4 times more prevalent in metabolic syndrome than in people with normal blood sugar metabolism. If effective action against metabolic syndrome is not taken, it will continue to worsen. Daily control of blood sugar levels is especially important to avoid many of the frightening effects of this age-and diet-related disease.... Levolar Forte is the most positive step you can take toward managing metabolic syndrome"
- "Levolar Forte is giving new hope to the millions of people who suffer from blood sugar metabolism disorders."

From the page where these claims appear, a link entitled "Levolar Research" takes consumers to a "News & Research" page, where you have posted several abstracts of scientific studies on ingredients in your Levolar Forte product. "Order Now" links on that page direct consumers to another page on your website where they can purchase your products, including Levolar Forte. Some of the study titles and abstracts on your "News & Research" page provide evidence of Levolar Forte's intended use in preventing and treating diabetes and other diseases. The following are two examples of studies whose titles and abstracts are used to market Levolar Forte for disease treatment and prevention on your website:

- "Maitake (Grifola frondosa) improve glucose tolerance of experimental diabetic rats"
- "The anti-hyperglycemic activity of the fruiting body of Cordyceps in diabetic rats induced by nicotinamide and strept020tocin."

Agaricus blazei Murill

- "A MUSHROOM WHICH CONTAINS SOME OF THE MOST POTENT ANTI CANCER SUBSTANCES YET FOUND!"
- "Agaricus Blazei is one of the most amazing medicinal mushrooms discovered. ... And it will have just as much impact upon the treatment of immuno-deficient diseases such as CANCER and AIDS, as did the discovery of antibiotics upon infections."
- "There are several active ingredients that have been identified in Agaricus blazei. Some of the more important of these are the following; Beta-(1-3)-D-glucan, Beta-(1-4)-a -D-glucan & Beta -(1-6)-D-glucan. Known collectively as Betaglucans ... [t]hey also appear to have have [sic] very powerful anti-tumor properties, even when used orally."
- "Modern research is showing that the main medicinal properties of this mushroom are anti-tumor and immune enhancement. In almost all of the studies published to date, the rate of tumor remission for all types of cancer has been amazingly high! Most of these studies have been done with rats or guinea pigs, but the hope is that results should be similar in humans."

In addition, the webpage for Agaricus blazei includes a link, "RESEARCH ARTICLES ON AGARICUS BLAZEI," which links to another page on your website where you provide several citations of scientific publications. Again., an "Order Now" link on that page directs consumers to the page on your website where they can buy your products, including Agaricus blazei. Several of the citations on the "Research Articles" page refer to the use of Agaricus blazei in preventing or treating cancer. These citations constitute further evidence of Agaricus blazei's intended use for those purposes. The following are examples of citations that are used to market Agaricus blazei for disease treatment and prevention on your website:

- **Biotherapy 1998;11(4):259-65.** Antitumor effect of a peptide-glucan preparation extracted from Agaricus blazei in a double-grafted tumor system in mice. Ebina T, Fujimiya Y Division of Immunology, Miyagi Cancer Center Research Institute,
- **Anticancer Res 1999 Jan-Feb;19(1A):113-8.** Tumor-specific cytotoxic and immunopotentiating effects of relatively low molecular weight products derived from the basidiomycete, Agaricus blazei Murill. Fujimiya Y, Suzuki Y, Katakura R, Ebina T Division of Immunology, Miyagi Cancer Center Research Institute, Natori, Japan.

K-9 Immunity

- "Dog Cancer Diagnosis? Here's Help."
- "K-9 Immunity™ is for use in dogs fighting cancer. ... First developed for addressing cancer in guide dogs for the blind, now available for your dog. K-9 Immunity™ has been used in thousands of dogs with cancer"
- The preceding claims appear on a webpage entitled "Dog Cancer and K-9 Immunity Help Your Dog Fight Cancer."
- "K-9 Immunity™ is a serious supplement that your vet should consider adding to the course of therapy he or she is recommending for treatment of your dog's cancer. It contains the most widely used anticancer compounds

in the world: PSK, PSP and Lentinan, as well as nearly 200 other closely related heteropolysaccharide immunomodulator compounds."

- "K-9 Immunity™ is for use in dogs fighting serious illness such as cancer."
- "The most important thing you can do to help your dog ... is to provide him or her with whatever you can to help optimize the Immune Function.... K-9 Immunity by Aloha Medicinals is the best that science has yet come up with for use as an adjunct in canine cancer therapy."
- "The combination of Transfer Factor Plus and K-9 Immunity seems to have the most powerful effect in turning cancer around, as well as being very quick acting. Most dogs [with cancer] on this combination experience dramatic improvements within the first ten days of use."
- "K9 Immunity is a Critical Care Formula for Dogs. This is the strongest immune support available specifically for dogs fighting cancer."
- "K9 Immunity was originally developed to treat cancer in guide dogs for the blind, and is now available for your companion. No prescription is required. Intended for adult dogs fighting cancer or facing other serious health challenges."

The webpage for K-9 Immunity also bears a disease claim in the form of a personal testimonial:

- "My husband ... made a video for our family and friends of our dog and the remarkable recovery since taking your products," followed by a video entitled, "Blue -The Canine Rocky," which depicts a dog recovering from liver cancer, among other things.

In addition, the webpage for K-9 Immunity includes a link, "New Study Demonstrates the Effects of Immune Modulation Therapy on Dogs with Cancer," which, when clicked, initiates a download of a study published in the *International Journal of Medicinal Mushrooms*. The study reports "the effectiveness" of K-9 Immunity and K9 Transfer factor "when used concurrently with chemotherapy." The link to the study is accompanied by "Order Now" links that direct consumers to another page on your website where they can buy your products, including K-9 Immunity and K-9 Transfer Factor. Your use of this study to promote the sale of K-9 Immunity and K9 Transfer Factor is further evidence of the intended use of these products to treat cancer.

K9 Transfer Factor

- "Transfer factors are compounds produced in the body which are required for proper immune system functioning. All mammals make these transfer factors, but often time [sic] in cancer the body's ability to manufacture sufficient Transfer Factors is impaired. K9 Transfer Factor is a specially formulated canine grade supplement for use with K-9 Immunity for increasing immune function. By itself, K9 Transfer Factor does not have much influence in the outcome of canine cancer. But its real value is in the way it enhances the absorption and bioavailability of the immune modulators in the K-9 Immunity."
- "When used along with the K-9 Immunity™, there is a synergistic effect greater than either product alone, and the overall efficacy is significantly enhanced. While K9 Transfer Factor is not absolutely required, it is HIGHLY recommended along with K9 Immunity to give the dog the best chance of a positive response to the treatment."
- "After more than three years of research and development, Aloha Medicinals has finally perfected the most effective grade of Transfer Factors for use in dogs fighting cancer."
- The claims above appear on a webpage entitled "K9 Transfer Factor I Help Your Dog Fight Cancer."
- "Transfer Factors are small protein molecules which significantly increases [sic] the bio-availability and the effectiveness of the K9 Immunity. This generally leads to a quicker and more positive outcome in cancer treatment. The combination of K9 Immunity and K9 Transfer Factor is especially recommended for dogs with Lymphosarcoma or Osteosarcoma [sic] cancer."

Dog Immune

- "What can I do to prevent my dog from getting cancer? This is a question we have heard every day for the last 8 years since we introduced K9 immunity. We have listened to your concerns, and as a result we have now developed the best daily immune supplement available for your dog. It is made from the same heteropolysaccharide immune modulators and immune proteins as our K9 Immunity and K9 Transfer Factor, but is formulated in a dry dog food base for use as a daily supplement."

These statements are supplemented by metatag keywords that you use to direct consumers to your website through Internet searches. For example, metatag keywords in the source code of your Levolar Forte webpage include "diabetes" and "type 2." Metatag keywords in the source code of your K-9 Immunity webpage include "cancer in dogs," "dog cancer" and "canine cancer."

Your "Immun-Assist," "Levolar Forte," "Agaricus blazei Murill," "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are drugs as defined by section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)], because they are intended for use

in the diagnosis, cure, mitigation, treatment, or prevention of disease. Further, "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are drugs as defined by section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(C)], because they are intended to affect the structure or function of the body of animals.

Moreover, "Immun-Assist," "Levolar Forte" and "Agaricus blazei Murill" are new drugs within the meaning of section 201(p) of the Act [21 U.S.C. § 321 (p)], because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)] a new drug may not be introduced or delivered for introduction into interstate commerce unless it is the subject of an FDA-approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). Your "Immune-Assist," "Levolar Forte" and "Agaricus blazei Murrill" products do not have approved applications and their introduction or delivery for introduction into interstate commerce violates section 301 (d) of the Act [21 U.S.C. § 331(d)]. Your sale of these products violates the law.

In addition, your "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are new animal drugs under section 201(v) of the Act [21 U.S.C. § 321 (v)], because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof [21 U.S.C. § 321(v)]. Under section 512(a) of the Act [21 U.S.C. § 360b(a)], "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" are unsafe because they are not subjects of approved New Animal Drug Applications (NADAs) or Abbreviated New Animal Drug Applications (ANADAs) under section 512(b) of the Act [21 U.S.C. § 360b(b)], Conditional Approvals under section 571 of the Act [21 U.S.C. § 360ccc] or Index

Listings under section 572 of the Act [21 U.S.C. § 360ccc-1]. As such, they are adulterated under section 501(a)(5) of the Act [21 U.S.C. § 351(a)(5)]. Under section 301(a) of the Act [21 U.S.C. § 331(a)], it is unlawful to introduce or deliver for introduction any adulterated drug into interstate commerce. Your sale of "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" without approved applications or index listings violates the law.

Your "Immun-Assist," "Levolar Forte," "Agaricus blazei Murill," "K-9 Immunity," "K9 Transfer Factor" and "Dog Immune" products are also misbranded within the meaning of section 502(f)(1) of the Act in that labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. Under section 301(a) of the Act [21 U.S.C. § 331 (a)], it is unlawful to introduce or deliver for introduction any misbranded drug into interstate commerce. Your sale of these products without adequate directions for use violates the law.

The violations mentioned above are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and for preventing recurrence of these, or other violations, to ensure that you comply with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, such as seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct these violations. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence; If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of documentation demonstrating that corrections have been made.

Your written response should be sent to Juliane Jung-Lau, Compliance Officer, San Francisco District, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. If you have any questions about this letter, please contact Ms. Jung-Lau at 510-337-6793.

Sincerely,
/S/

Barbara Cassens
District Director