Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District Office
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Phone 781.587.7500
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WARNING LETTER
CMS # 443379

VIA UNITED PARCEL SERVICE

January 20, 2015

Rene P. Guay
President
Chaga Mountain, Inc.
926 Main St.
Dennistown, ME 04945-3008

Dear Mr. Guay:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 926 Main St, Dennistown, Maine from September 23, 2014 through October 1, 2014. Based on our inspection and subsequent review of your firm's website, we found serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and its implementing regulations. You can find the Act and FDA's regulations through links on FDA's home page at http://www.fda.gov.

Unapproved New Drug

The FDA reviewed your website at http://www.chagamountain.com in November of 2014, and has determined that you take orders there for your products Chaga Mushroom Tincture/Extract – Alcohol Free, Chaga Mushroom Tea Bags, Chaga Mushroom Powdered Loose Teas, Chaga Skin Cream and Lip Balm with natural ingredients including natural Essential oils which the website promotes for conditions that cause the products to be drugs under section 201(g)(1)(B) and/or section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(B) and/or § 321(g)(1)(C)]. The claims on your website establish that the products are intended for use in the cure, mitigation, treatment or prevention of disease and/or articles intended to affect the structure or any function of the human body, rendering them drugs under the Act. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

We note that Chaga Mushroom is an ingredient in all Chaga Mushroom products offered for sale on your firm's website including Chaga Mushroom Tincture/Extract – Alcohol Free, Chaga Mushroom Tea Bags, Chaga Mushroom Powdered Loose Teas, Chaga Skin Cream and Lip Balm with natural ingredients including natural Essential oils.

Anti-cancer: "[A]n anti-cancer…Anti-Cancer… highly potent anti-cancer agents…later studies also suggest this compound being a broad inhibitor of other cancerous tumors including aneuroectodermal tumors (such as neuroblastoma, medulloblastoma, glioblastoma and Ewing's sarcoma), brain-tumors, human gliomas, leukemia, human colon carcinoma and human prostate adenocarcinoma, head and neck squamous carcinoma cells, lung, colorectal, breast, and cervical cancer… was initially known for its high cytotoxicity against human melanoma cancer cells… has been known to aid in the prevention of cancer and AIDS…hailed as one of the greatest new developments in the nutritional treatment of cancer…protects against radiation…enables the body to change its response to tumors….making it effective in the treatment of cancer as well as other degenerative diseases…show various biological activities, including anti-tumour, anti-viral, hypoglycaemic, anti-oxidant and cyto-protective… exhibit anti-tumor properties, destroying Walker 256 Carcinosarcoma cancer cells and MCF-7 human adenocarcinoma mammary cells…exhibit strong cytotoxicity towards carcinoma cells… Aqueous extracts of chaga also inhibited growth of human hepatoma cells via arrest of the cell cycle in Go/G1 phase and inducing selective apoptosis…a direct effect on the mitochondria of cancer cells"

HIV, AIDs: "[F]or Fighting HIV…Chaga has demonstrated anti-HIV, antibacterial, anti-malarial, anti-inflammatory and anthelmintic properties… Anti-HIV…Water-soluble lignins isolated from Chaga, inhibited HIV protease…used for high cholesterol, diabetes, cancer, and HIV/AIDS… possess many favorable biological properties such as anti-cancer, anti-HIV-1 (human immunodeficiency virus type-1)…used for asthma; diabetes; high blood pressure; acquired immunodeficiency syndrome (AIDS)…"

Antiviral, Antimicrobial, Antifungal, Anti-Candida, Anti-Malarial: "[C]haga is also antiviral, antifungal, antimicrobial and anti-Candida… Chaga kills or inhibits growth or replication by destroying or suppressing reproduction of bacteria…are antibacterial…Anti-Malarial… antimalarial…Anthelmintic…Antivira…Antifungall…Antimicrobial properties in Chaga…Anti-Candida…antibacterial, anti-malarial, anti-inflammatory, and anthelmintic activities… have anti-bacterial, anti-viral, anti-tumor, anti-inflammatory, antiallergenic.. antibacterial and antifungal properties… It's also an anti-bacterial, lowers cholesterol and reduces candida…"

Anti-inflammatory: "[C]haga has properties that help to…inflammation …have strong anti-inflammatory…properties…acts as anti-inflammatory in the body…"

Arthritis: "[H]as also been used to treat arthritis, prostate problems, corneal ulcers, burn injuries, inflammatory diseases, inflammatory bowel disease, and long-term damage from exposure to smoke and radiation, and to prevent side effects of cancer drugs…"

Influenza, H1N1: "[U]sed for…flu (influenza), H1N1 (swine) flu, allergies, hepatitis, Lyme disease, asthma, ear infections… has shown activity against influenza (flu) viruses A and B and various cancer cells…"

Wilson's Disease, Bronchitis, Crohn's disease, multiple sclerosis, arthritis, Alzheimer's Disease, ADHD, Down Syndrome, Hodgkin's Lymphoma, Tuberculosis, Hepatitis: "[U]lcerative colitis and Crohn's disease, fibromyalgia, rheumatoid arthritis, and multiple sclerosis …works as an antioxidant to help prevent cancer and heart disease…benefit a wide variety of diseases, including

rheumatoid arthritis and Alzheimer's Disease… and skin conditions such as psoriasis, eczema…Other uses include treating attention deficit-hyperactivity disorder (ADHD), blunted sense of taste (hypogeusia), ringing in the ears (tinnitus), severe head injuries, Crohn's disease, Alzheimer's disease, Down syndrome, Hansen's disease, ulcerative colitis, peptic ulcers and promoting weight gain in people with eating disorders such as anorexia nervosa… It is also used for sickle cell disease and inherited disorders such as acrodermatitis enteropathica, thalassemia, and Wilson's disease… BronchitisCrohn's Disease (CD)…Diabetes… Hodgkin's Lymphoma… Hepatitis…"

Erectile dysfunction: "[F]or benign prostatic hyperplasia (BPH), male infertility, erectile dysfunction (ED), weak bones (osteoporosis), rheumatoid arthritis, and muscle cramps associated with liver disease…"

Chaga Skin Cream and Lip Balm with natural ingredients including natural Essential oils: "[A]n enzyme that repairs cells and reduces the damage done to them…is key to the production of healthy fibroblasts (skin-building cells)…acts as… anti-inflammatory in the body…protects the cells' cytoplasm… protects their mitochondria from free radical damage…used to treat arthritis, prostate problems, corneal ulcers, burn injuries, inflammatory diseases, inflammatory bowel disease, and long-term damage from exposure to smoke and radiation, and to prevent side effects of cancer drugs…In its topical form, it may help to reduce facial wrinkles, scar tissue, heal wounds and burns, lighten dark or hyperpigmentation, and protect against harmful UV rays."

Your products are not generally recognized as safe and effective for the above- referenced uses and, therefore, the products are "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)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. 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.

Furthermore, your "Chaga Mushroom Tincture/Extract – Alcohol Free, Chaga Mushroom Tea Bags, Chaga Mushroom Powdered Loose Teas, Chaga Skin Cream and Lip Balm with natural ingredients including natural Essential oils"products are offered for conditions that 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 layperson can use the drugs safely for their intended uses. Thus, these drugs are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that their labeling fails to bear adequate directions for uses. The introduction of or delivery for introduction into interstate commerce of these products is a violation of § 301(a) of the Act [21 U.S.C. § 331(a)].

Adulterated Dietary Supplements

Even if your Chaga Mushroom Tincture/Extract – Alcohol Free, Chaga Mushroom Tea Bags, and Chaga Mushroom Powdered Loose Teas products did not have therapeutic claims which make them unapproved drugs, these dietary supplement products are adulterated under section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet the Current Good Manufacturing Practice (CGMP) requirements for dietary supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111).

Specifically, during our inspection, our investigators observed the following significant violations, which were noted on Form FDA 483, Inspectional Observations, issued to you on October 1, 2014. We received your written response, dated October 7, 2014 and received by the FDA's New

England District office on October 17, 2014, to the Form FDA 483. Your response is discussed in more detail below.

1. You failed to establish identity specifications for each component that you use in the manufacture of a dietary supplement, as required by 21 CFR 111.70(b). Specifically, you failed to establish component specifications for identity, purity, strength, composition and limits on contaminants for your Chaga Mushroom Teas and Chaga Mushroom Tincture/Extract - Alcohol Free Dietary Supplements. Please note that once you have established the identity specifications for each component, you must verify that the specifications are met in accordance with 21 CFR 111.75(a)(1)(i) and 21 CFR 111.75(a)(2), and you must make and keep records in accordance with 21 CFR 111.95(b).

We acknowledge your response, dated October 7, 2014, to the Form FDA 483, Inspectional Observations issued at the close of the inspection. We cannot assess the adequacy of your response because sufficient evidence was not provided to demonstrate specifications for identity, purity, strength, composition, and limits on contaminants have been established for all components used in the manufacture of the teas and tinctures.

You also failed to conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient prior to its use, as required by 21 CFR 111.75(a)(1)(i) unless FDA grants an exemption under 21 CFR 111.75(a)(1)(ii). Specifically, you stated to our investigator that you do not conduct identity testing on any of the components used to produce dietary supplement products you manufacture.

We acknowledge your response, dated October 7, 2014, to the Form FDA 483, Inspectional Observations issued at the close of the inspection. We find your response to be inadequate in that you did not address the testing of components used by your firm to manufacture dietary supplement products.

2. You failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement you manufacture and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required by 21 CFR 111.205 and 21 CFR 111.210. For example, you stated to our investigator the MMRs utilized to manufacture Chaga mushroom tea and Chaga mushroom non-alcohol (glycerin) based tincture extract dietary supplements failed to identify specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of a dietary supplement.

We acknowledge your response, dated October 7, 2014, to the Form FDA 483, Inspectional Observations issued at the close of the inspection. We find your response to be inadequate because your Master Manufacturing Records for the Chaga Mushroom Teas and Chaga Mushroom Tincture/Extract - Alcohol Free Dietary Supplements failed to include the following requirements:

a. The strength, concentration, weight or measure of each dietary ingredient for each batch size [21 CFR 111.210(a)]

b. An accurate statement of the weight of measure of each component to be used [21 CFR 111.210(c)].

c. A statement of intentional overage amount of a dietary ingredient [21 CFR 111.210(e)]

d. A statement of theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process and the expected yield when you finish manufacturing the dietary supplement [21 CFR 111.210(f)]

e. A representative label, or a cross-reference to the physical location of the actual or representative label [21 CFR 111.210(g)]

f. Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the MMR [21 CFR 111.210(h)(1)];

g. Procedures for sampling and a cross reference to procedures for tests or examinations [21 CFR 111.210(h)(2)]

3. Your batch production records (BPR) failed to include complete information related to the production and control of each batch, as required by 21 CFR 111.255(b) and 21 CFR 111.260. Specifically, your BPRs for your Chaga Mushroom Teas and Chaga Mushroom Tincture/Extract – Alcohol Free products did not include the following information:

a. The identity of equipment and processing lines used in producing the batch [21 CFR 111.260(b)];

b. The date and time of maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch. [21 CFR 111.260(c)];

c. A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing [21 CFR 111.260(f)];

d. The results of any testing or examination performed during batch production or a cross-reference to such results [21 CFR 111.260(h)];

e. Documentation that the finished dietary supplement meets established specifications in accordance with § 111.70(e) and (g)[21 CFR 111.260(i)];

f. Documentation at the time of performance that quality control personnel performed required actions [21 CFR 111.260(1)];

g. Documentation at the time of performance of any required material review and disposition decision [21 CFR 111.260(m)];

h. Documentation at the time of performance of any reprocessing [21 CFR 111.260(n)]

We acknowledge your response, dated October 7, 2014, to the Form FDA 483, Inspectional Observations issued at the close of the inspection. We find your response to be inadequate in that your submitted BPRs are missing required information. Additionally, the example BPR you provided for the Chaga Mushroom Tincture/Extract - Alcohol Free Dietary Supplement product refers to a Theoretical Batch Size with a notation of "**(b)(4)**" and "**(b)(4)**." A master manufacturing record for a specific batch size must be created and supported by corresponding batch records.

4. You failed to establishing and follow written procedures which described your quality control operations as required by 21 CFR 111.103, nor were you able to provide evidence that you have

implemented quality control operations in your manufacturing, packaging, labeling, and holding operations as required by 21 CFR 111.65.

5. You failed to establish product specifications for the identity, purity, strength, and composition of the finished batch of each dietary supplement, and for those limits on those types of contaminations that may adulterate, or that may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement, as required by 21 CFR 111.70(e).

Once your firm has established product specifications for the identity, purity, strength, composition, and limits on contaminants for each finished dietary supplement, you must verify that the specifications are met in accordance with 21 CFR 111.75(c) and you must make and keep records in accordance with 21 CFR 111.95(b).

Misbranded Dietary Supplements

Further, even if your "Chaga Mushroom Tincture / Extract –Alcohol Free" product was not an unapproved new drug, it would still be a misbranded dietary supplement within the meaning of section 403 of the Act [21 U.S.C. § 343]. The inspection revealed the following violations of labeling requirements for dietary supplements,

1. Your "Chaga Mushroom Tincture/Extract –Alcohol Free" product is misbranded within the meaning of 403(q)(5)(F) of the Act [21 U.S.C. 343 (q)(5)(F)] because it fails to bear nutrition information ("Supplements Facts" panel) as required by 21 CFR 101.36.

This letter is not intended to be an all-inclusive list of violations which exist in connection with your products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations described above and prevent their further recurrence. Failure to promptly correct these violations may result in enforcement action, without further notice, including, without limitation, seizure and/or injunction.

Section 743 of the Act [21 U.S.C. § 379j-31] authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determining whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses incurred in connection with FDA's arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees [21 U.S.C. § 379j-31(a)(2)(B)]. For a domestic facility, FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct the violations noted above and prevent their future recurrence. You should include in your response documentation and any other useful information that would assist us in evaluating your corrections. If you cannot complete the corrective actions within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Please send your written reply to the Food and Drug Administration, Attention: Mr. Todd Maushart, Compliance Officer, One Montvale Ave, Stoneham, MA 02180. If you have questions regarding any issues in this letter, please contact Mr. Maushart at 781-587-7578

Sincerely,
/S/
Mutahar Shamsi
District Director
New England District Office