



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
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Nashville, TN 37217-1003
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April 25, 2011

WARNING LETTER NO. 2011-NOL-14

**UNITED PARCEL SERVICE
DELIVERY SIGNATURE REQUESTED**

Elizabeth I. Smith, Owner/President
Natural Path/Silver Wings, LLC
1771 Highway 70, Suite 102
Kingston Springs, Tennessee 37082

Dear Ms. Smith:

This letter concerns your firm's marketing and distribution of the products Natural Path Silver Wings Colloidal Silver Immune Support Herbal Tincture Spray 125 PPM, Natural Path Silver Wings Colloidal Silver Immune Support (50 PPM, 250 PPM, and 500 PPM), Natural Path Silver Wings Silver Aloe Gel-w/Tea Tree Oil and HMD™ Heavy Metal Detox. The U.S. Food and Drug Administration (FDA) reviewed the labeling for these products, including your promotional brochures. On January 21, 2011, we also reviewed the websites www.naturalpathsilverwings.com and www.detoxmetal.com, which are referenced on some of your products' labels. As described below, these products are unapproved new drugs in violation of Sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 *United States Code* (U.S.C) §§ 355(a) and 331(d)], and are misbranded drugs in violation of Sections 502 and 502(f) of the Act [21 USC §§ 352(f)].

In addition, an inspection of your firm conducted on August 3 through 5, 2010, revealed significant violations of Current Good Manufacturing Practice (CGMP) requirements. It should

be noted, that even if some of these products were dietary supplements, which they are not, they would be adulterated under Section 402(g)(1) of the Act [21 USC § 342(g)(1)].

Unapproved New Drugs/Misbranded Drugs

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man are drugs as defined in Section 201(g)(1)(B) of the Act [21 U.S.C § 321(g)(1)(B)]. Based on the claims in your labeling, including your websites, we have determined your products are promoted for conditions which cause them to be drugs under Section 201 (g)(1)(B).

The following claims found on your product labeling, including but not limited to your websites, cause your products to be drugs:

HMD™ Heavy Metal Detox

- (An ingredient in this product) "Chlorella Growth Factor ... reduces high blood pressure and serum cholesterol levels."
- "Chlorella Growth Factor (CGF) ... has many other benefits such as ... lower blood sugar levels ... "
- (An ingredient in this product) "Coriandrum sativum ... commonly referred to as Cilantro ... has been well-researched and has been found to have the following benefits ... Blood sugar lowering properties ... Anti-inflammatory properties ...Antimicrobial properties ... laboratory tests showed is twice as effective as the antibiotic gentamicin at killing Salmonella."
- (From website, www.detoxmetal.com) link to your Research Article entitled "The Discovery of a Unique Natural Heavy Metal Chelator" by Dr. George J. Georgious, Ph.D., N.D., DSc (AM) that also listed the above claims.
- (Testimonials) "I just wanted to tell you for the first time since our son was diagnosed with severe heavy metals poisoning at three years old by his pediatrician; he is FINALLY excreting mercury after taking the HMD."

Further, your www.detoxmetal.com website cites a number of articles under the heading "Chlorella References" regarding the use of this ingredient in your HMD™ Heavy Metal Detox for treatment or prevention of fibromyalgia and other diseases. When scientific publications are used commercially by the seller of a product to promote the product to consumers, such publications may become evidence of the product's intended use. For example, under Title 21, Code of Federal Regulations, Part 101.93(g)(2)(iv)(C) [21 CFR 101.93(g)(2)(iv)(C)], a citation of a publication or reference in the labeling of a product is considered 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.

The following are examples of reference citations used to market your product for disease treatment and prevention on your website:

- "Merchant RE; Carmack CA; Wise CM. Nutritional supplementation with Chlorella pyrenoidosa for patients with fibromyalgia syndrome: a pilot study. Department of Anatomy and Internal Medicine, Virginia Commonwealth University, Medical College of Virginia, Richmond, VA 23298-0709, USA. rmerchan@hsc.vcu.edu"
- "Tanaka K, Yamada A, Noda K, et al. Oral administration of a unicellular green algae, Chlorella vulgaris, prevents stress-induced ulcer. *Planta Med* 1997 Oct;63(5):465-6."
- "Ibusuki K; Minamishima Y. Effects of Chlorella vulgaris extracts on murine cytomegalovirus infections. *Nat Immun Cell Growth Regul* 1990;9(2):121-8."

The above claims cause your HMD™ Heavy Metal Detox product to be a drug, as defined in Section 201(g)(1)(B) of the Act [21 U.S.C § 321(g)(1)(B)]. Because this product is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling, it is also a new drug as defined in Section 201(p) of the Act [21 U.S.C § 321(P)]. Under Sections 301(d) and 505(a) of the Act [21 U.S.C §§ 331(d) and 355(a)] a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of HMD™ Heavy Metal Detox without such an approved application violates these provisions of the Act.

HMD™ Heavy Metal Detox is a prescription drug as defined in Section 503(b)(1)(A) of the Act [21 U.S.C § 353(b)(1)(A)], because, in light of its toxicity or other potential for harmful effect, the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer it.

According to Section 502(f)(1) of the Act [21 U.S.C § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved prescription drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson (21 CFR 201.100(c)(2) and 201.115). Because there is no FDA-approved application for your firm's HMD™ Heavy Metal Detox its labeling fails to bear adequate directions for its intended use, causing it to be misbranded under Section 502(f)(1) of the Act [21 U.S.C § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of this misbranded product violates Section 301(a) of the Act [21 U.S.C § 331(a)].

Natural Path Silver Wings Colloidal Silver Immune Support Herbal Tincture Spray 125 PPM, Natural Path Silver Wings Colloidal Silver Immune Support (50 PPM, 250 PPM, and 500 PPM), Natural Path Silver Wings Silver Aloe Gel-w/Tea Tree Oil

- "Kappa Laboratories (Mt. Sinai Hospital) completed a Time Kill Study with NP/SW [Natural Path/Silver Wings] colloidal silver. The study showed results of killing the gram positive and gram negative bacteria (99.9%) and no re-growth for 48 hours. Our colloidal silver was "consistently effective in demonstrating Bactericidal Activity" after the initial kill of the bacterial."

The above claim regarding Natural Path/Silver Wings colloidal silver appears to apply to all of your products containing colloidal silver: Natural Path Silver Wings Colloidal Silver Immune Support 50 PPM, 250 PPM, 500 PPM, Natural Path Silver Wings Colloidal Silver Immune Support Tincture Spray 125 PPM, and Natural Path Silver Wing Silver Aloe Gel-w/Tea Tree Oil. This claim causes these products to be drugs, as defined in Section 201(g)(1)(B) of the Act [21 U.S.C § 321(g)(1)(B)].

As drug products containing colloidal silver and with disease claims on their labeling, Natural Path Silver Wings Colloidal Silver Immune Support 50 PPM, 250 PPM, 500 PPM, Natural Path Silver Wings Colloidal Silver Immune Support Tincture Spray 125 PPM, and Natural Path Silver Wing Silver Aloe Gel-w/Tea Tree Oil are subject to 21 CFR 310.548, which states in subsection (a) "[t]here is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for over-the-counter (OTC) use in the treatment or prevention of any disease." Under 21 CFR 310.548(b), any OTC drug product containing colloidal silver ingredients or silver salts that is labeled, represented, or promoted for the treatment and/or prevention of any disease is regarded as a new drug under Section 201(p) of the Act [21 USC § 321(p)]. Under Sections 301(d) and 505(a) of the Act [21 U.S.C §§ 331(d) and 355(a)] a new drug may not be introduced or delivered for introduction into interstate

commerce unless an FDA-approved application is in effect for it. Your sale of Natural Path Silver Wings Colloidal Silver Immune Support 50 PPM, 250 PPM, 500 PPM, Natural Path Silver Wings Colloidal Silver Immune Support Tincture Spray 125 PPM, and Natural Path Silver Wing Silver Aloe Gel-w/Tea Tree Oil without such approved applications violates these provisions of the Act.

Additionally, per 21 CFR 310.548(b), any product containing colloidal silver ingredients or silver salts which is labeled, represented, or promoted for the treatment and/or prevention of any disease, and is not the subject of an FDA-approved application, is misbranded under Section 502 of the Act [21 U.S.C § 352].

Furthermore, your Colloidal Silver products, including Natural Path Silver Wings Colloidal Silver Immune Support 50 PPM, 250 PPM, 500 PPM, Tincture Spray 125 PPM, and Natural Path Silver Wings Silver Aloe Gel are also misbranded under Section 502(f)(1) of the Act [21 U.S.C § 352(f)(1)] because they do not bear adequate directions for their intended uses because the labeling for these products do not explain how to use the colloidal silver products to achieve the bactericidal effect referenced in labeling.

Adulterated Dietary Supplements

As described above, your products are unapproved and misbranded drugs. However, even if some or all of your products were dietary supplements, which they are not, the products could not be lawfully marketed because they would be adulterated within the meaning of Section 402(g)(1) of the Act [21 U.S.C § 342(g)(1)] because they have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements, as described below.

We reviewed your response of August 16, 2010, and note it lacks sufficient corrective actions. Specific violations observed during the inspection include, but are not limited to, the following:

- a) Your firm 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(a).

Specifically, your firm was unable to provide written master manufacturing records for the products Natural Path Silver Wings Colloidal Silver Immune Support Dietary Supplement and HMD™ Heavy Metal Detox Dietary Supplement manufactured at your facility.

Your response does not adequately address your failure to meet this requirement. Contrary to your promise to develop and implement a Master Manufacturing Record for each of your products within 30 days, your response indicated you had a MMR for these products, but you didn't include them in your response for our evaluation.

b) You did not collect representative samples of each unique lot of components used in your products, as required by 21 CFR 111.80(a).

Specifically, a representative sample of mild silver protein component was not collected for your Colloidal Silver Immune Support Dietary Supplement product and representative samples of chlorella growth factor, cilantro leaf (*coriandrum sativum*), and chlorella homaccord components were not collected for your Heavy Metal Detox Dietary Supplement product.

You did not collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distribute, as required by 21 CFR 111.83(a).

Specifically, reserve samples were not collected for your Colloidal Silver Immune Support Dietary Supplement and Heavy Metal Detox Dietary Supplement products.

Your responses regarding the collecting of representative and reserve samples are inadequate as you provided no evidence the above representative samples or reserve samples were collected. Further, you provided no reassurance that representative or reserve samples would be collected. For instance, your quality control personnel must ensure that required reserve samples are collected and held for one year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples.

Your responses to the Form FDA 483 observations numbers two and three concerning quality control personnel appear to be adequate. You indicated you appointed one person to perform Quality Control operations with no manufacturing duties. You also indicated you intend to provide GMP training to your quality control management within six months. We will verify these changes during our next inspection.

The violations cited in this letter are not intended to be an all-inclusive statement of violations which exist at your facility and in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing

their recurrence or the occurrence of other violations. It is your responsibility to assure your firm complies 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, including, without limitation, seizure and injunction. Other federal agencies may take this warning letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending new drug applications listing your facility as a supplier or manufacturer until the above violations are corrected.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. If you no longer manufacture or market the products described in this letter, your response should so indicate, including the reasons, and the date on which, you ceased production.

Please address your reply to Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding the contents of this letter, please contact Ms. Asente at (504) 219-8818, extension 104.

Sincerely,

/S/

Laurie C. Farmer
Acting District Director
New Orleans District