MusclMasster, LLC 8/30/17

U.S. FOOD & DRUG ADMINISTRATION

Denver District Office
P.O. Box 25087
Denver, CO 80225

August 30, 2017

WARNING LETTER

Via UPS Overnight

Tommy L. Phillips, Managing Member
MusclMasster, LLC
4565 Kipling St.
Wheat Ridge, CO 80033

Ref: # DEN-17-18-WL

Dear Mr. Phillips:

From February 15-23, 2017, the U.S. Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility located at 4565 Kipling St., Wheat Ridge, Colorado. Based on the inspection, a review of the product labels collected during the inspection, and a review of your website at www.thegreenherb.com, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You may find the Act and FDA regulations through links on FDA's website at **www.fda.gov (http://www.fda.gov/)**.

Additionally, after post-inspectional review of your website, www.thegreenherb.com, the inspection of your manufacturing facility was re-opened on March 30, 2017. During the March 30-May 12, 2017, inspection, samples were collected of your bulk ingredient **(b)(4)** (extract and leaf forms) and the finished dietary supplement "AL-ER-G." Laboratory analyses conducted by the FDA determined that ingredients identified as "**(b)(4)**" and the AL-ER-G products collected at your facility contain ephedrine alkaloids. The use of ephedrine alkaloids in your dietary supplement product AL-ER-G causes the product to be adulterated within the meaning of section 402(f)(1)(A)(ii) of the Act [21 U.S.C. § 342(f)(1)(A)(ii)] in that it is a dietary supplement that contains a dietary ingredient that presents

a significant or unreasonable risk of illness or injury under ordinary conditions of use (see also 21 Code of Federal Regulations (CFR) 119.1). We acknowledge that you stated that you voluntarily destroyed all Ephedra-containing ingredients and dietary supplement products in your possession during the inspection and that you issued a voluntary nationwide recall for the product AL-ER-G.

Unapproved New Drugs/Misbranded Drugs

FDA reviewed your website at www.thegreenherb.com in July 2017 and has determined that you take orders there for the products Vas-Q-Lar, Vir-L IV, and Nu Woman. FDA also reviewed product labels collected during the February 2017 inspection. The claims on your labels and website establish that these products are drugs under section 201(g)(1)(B) of the Act [21 USC § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

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

Under the "About Us" tab, titled, "Get To Know Us!"

- "I started taking herbs for diabetes, Linda for chronic back pain, and …Jesse….for infected tonsils. Results were almost immediate."

Under the Testimonials tab

- "I had been suffering with Acid Reflux for 18 years. I had taken medication for it all those years. I could not stop the medication for more than three days without having extreme pain. After my appointment…it took only 3 weeks to be able to stop the medications and 3 months to be symptom free."
- "I had an issue with my lymph nodes hurting for about 9 years….I started taking Vas-Q-lar Clear and after about 2 months I woke up one day and my lymph nodes weren't hurting anymore!!!"
- "I came to The Green Herb …after my stroke…got me on an herbal program to heal from that and to also get rid of my severe case of Candida, parasites and nutrient deficiencies we saw in the Live blood test."

Under the Products tab

Vas-Q-Lar

- "Weakness in your circulatory system can lead to many different problems including hypertension, angina, aneurysm, and even strokes…If you want botanicals that will naturally nourish and help your body strengthen the circulatory system, you should try Vas-Q-Lar Renew."
- "[M]ay slow the progression of Alzheimeris [sic] disease…beneficial for asthma, dementia, depression, eczema, headaches, heart and kidney disorders, and tinnitus (ringing of ears)"
- "Mullien Leaf … aids in healing respiratory ailments, asthma, bronchitis, diarrhea, sinus congestion; soothing to any inflammation and relieves pain; acts to relieve spasms & clears the lungs; Mullein is a soothing demulcent for respiratory ailments; it clears congestion and aids in getting rid of warts; useful for asthma, bronchitis, difficulty breathing, earache, hay fever and swollen glands"
- "Marshmallow Root – soothes irritated membranes & tissues, expectorant, abundant mucilage, demulcent…"
- "Hawthorne Berries – dilates the coronary blood vessels, lowering blood pressure and natural cholesterol lowering …useful for anemia, cardiovascular and circulatory disorders…high cholesterol"
- "Echinacea Angustifolia Root … stimulates the body to fight bacterial and viral infection…reduces inflammation"

- “Korean Ginseng Root … lowers blood pressure, lowers triglycerides and LDL or bad cholesterol…fights… depression”
- “Nettle Leaf – …expectorant, pain reliever… good for benign prostatic hyperplasia, anemia, arthritis, rheumatism, hay fever, and other allergic disorders, kidney problems, and malabsorption syndrome; improves goiter, inflammatory conditions and mucous conditions of the lungs”

Vir-L IV

- “[H]elp fight viral infections, cancer, depression…”
- “Pau D’arco Bark – potential anti-fungal, anti-tumor & anti-canceral properties”
- “[E]nhances antibody production”
- “[A]nti-viral properties”
- “[A]nti-inflammatory”

Nu Woman

- “[S]edative to pain and distress in kidneys and bladder”

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

Vas-Q-Lar

- “[I]ssues associated with: Hypertension, angina, strokes”

Vir-L IV

- “[I]ssues associated with: Viral Infections”

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)(1) of the Act [21 USC § 321(p)(1)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 USC §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Vas-Q-Lar and Vir-L IV products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment. Therefore, it is impossible to write adequate directions for a layperson to use these products safely for their intended purposes. Accordingly, Vas-Q-Lar and Vir-L IV fail to bear adequate directions for their intended use and, therefore, the products are 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 these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

Dietary Supplement CGMP Violations

The dietary supplement products that you manufacture, package, label, and/or hold are adulterated within the meaning of section 402(g)(1) of the Act [21 U.S.C. 342(g)(1)] because the products have been prepared, packed, or held under conditions that do not meet the Current Good Manufacturing Practice (CGMP) regulations for dietary supplements, 21 CFR Part 111. Additionally, many of your products are not labeled as dietary supplements, and therefore do not meet the definition of a dietary supplement (*see* section 201(ff)(2)(C) of the Act [21 U.S.C. § 321(ff)(2)(C)]); however, we note that the product labels for many of your products that are not properly labeled as dietary supplements include directions for use as a "food supplement" and a statement that closely resembles the statement required under section 403(r)(6)(C) of the Act [21 U.S.C. § 343(r)(6)(C)], for dietary supplements that make certain labeling claims. Based on your use of this language, it appears you may intend to market your Nu-Woman, Nu Man Plus, Vir-L IV, AL-ER-G, and Vas-Q-Lar products as dietary supplements. Even if these products were dietary supplements—and if your Vas-Q-Lar, Vir-L IV, and Nu Woman were not unapproved new drugs or misbranded drugs—they would be adulterated dietary supplements under 402(g)(1) of the Act [21 U.S.C. 342(g)(1)] because the products were prepared, packed, or held under conditions that do not meet the CGMP regulations for dietary supplements in 21 CFR Part 111.

We acknowledge receipt of your written response to the deficiencies reported to you on the FDA-483, Inspectional Observations, provided to you at the close of our recent inspection. However, we are unable to evaluate the adequacy of your corrective action because you did not provide documentation to assist us in verifying any corrective actions you state you are taking, and you did not address all of the deficiencies identified on the FDA-483.

The significant violations documented during the inspection include, but are not limited to, the following:

1. Your firm failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, as required by 21 CFR 111.103 and 21 CFR 111.140(b). Specifically, you have no written procedures for the responsibilities of the quality control operations.

Further, your quality control operations are insufficient in that your personnel failed to conduct a material review and make a disposition decision when a batch deviated from the master manufacturing record (MMR), as required by 21 CFR 111.113(a)(2). For example, **(b)(4)**" [sic] was used in the manufacture of **(b)(4)** brand **(b)(4)**, batch **(b)(4)** and **(b)(4)**; however, it is not listed as an ingredient on the MMR, batch record, or product label. There is no documentation of a quality control material review and disposition decision for use of an ingredient not listed on the MMR.

We have reviewed your response received on March 28, 2017. In your response, you state that the corrective actions are being completed; however, we are unable to evaluate the adequacy of your corrective action because you have not provided documentation that you have established written procedures for the responsibilities of the quality control operations, including those for conducting a material review and making a disposition decision.

2. Your firm failed to establish component specifications that are necessary to ensure that specifications for the identity, purity, strength, and composition of dietary supplements manufactured using the components are met, as required by 21 CFR 111.70(b)(2). Specifically, you have not established specifications for any of the components used in the production of the dietary supplement products you manufacture, including, but not limited to:

- Black cohosh root used in the production of The Green Herb brand Nu-Woman capsules
- Milk Thistle used in the production of **(b)(4)** capsule
- Pau d'Arco Bark used in the production of The Green Herb brand Vir-L-IV
- Vitamin E used in the production of **(b)(4)** brand **(b)(4)**

- Yohimbe Bark used in the production of The Green Herb brand Nu-Man Plus

Once you have established component specifications and before using a component, you must conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, as required by 21 CFR 111.75(a)(1)(i), unless you petition the agency under 21 CFR 111.75(a)(1)(ii) and the agency exempts you from such testing; you must also confirm the identity of other components and determine whether other applicable component specifications established in accordance with 21 CFR 111.70(b) are met, as required by 21 CFR 111.75(a)(2). You must also ensure that the tests and examinations that you use to determine whether the specifications are met are appropriate, scientifically valid methods, as required by 21 CFR 111.75(h)(1), and you must make and keep records of the specifications established, as required by 21 CFR 111.95(b)(1).

We have reviewed your response received on March 28, 2017. In your response, you state that you have begun the process to purchase equipment to verify the identity of ingredients. We are unable to evaluate the adequacy of your corrective actions because you have not provided documentation that you have established component specifications.

3. Your firm failed to establish specifications for each dietary supplement that you manufacture for the identity, purity, strength, and composition for the finished batch of the dietary supplement, and for limits on those types of contamination 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). Specifically, you have not established finished product specifications for the identity, purity, strength, composition, and limits on contamination for any of the dietary supplement products you manufacture. This includes, but is not limited to, the following finished products manufactured and distributed by your firm:

- The Green Herb brand Nu-Woman
- The Green Herb brand Vir-L-IV
- **(b)(4)** brand **(b)(4)**
- **(b)(4)** Capsule
- The Green Herb brand Nu-Man Plus

Once you have established the required specifications, you must verify your finished dietary supplements meet those product specifications, as required by 21 CFR 111.75(c).

We have reviewed your response, received on March 28, 2017. You state you have established limits for all heavy metals, microbiologicals, and other contaminants that may be contained in your products; however, we are unable to evaluate the adequacy of your corrective action because you have not provided documentation that you have established finished product specifications for identity, purity, strength, composition, and contamination.

Your firm failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you manufactured, and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required under 21 CFR 111.205(a). Specifically, your MMR does not contain all the required elements under 21 CFR 111.210. Examples of deficiencies observed during the inspection include the following:

- A complete list of components to be used [21 CFR 111.210(b)]. Your **(b)(4)** Capsule, batch **(b)(4)** and **(b)(4)**, do not include **(b)(4)** and Vitamin B-5 as ingredients in the MMR; however, both these ingredients are listed on the product label;
- A statement of theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement [21 CFR 111.210(f)];

- A description of packaging and a representative label or cross-reference to the physical location of the actual or representative label [21 CFR 111.210(g)];
- Written instructions, including the following:

  o Procedures for sampling and a cross-reference to procedures for tests or examinations [21 CFR 111.210(h)(2)];
  o Specific actions necessary to perform and verify points, steps, or stages 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 (e.g., specific actions necessary to perform and verify the mixing/blending and encapsulation steps) [21 CFR 111.210(h)(3)].

We have reviewed your response received on March 28, 2017. In your response, you state that you have included all necessary elements in your MMR, except for a statement of theoretical yield; however, we are unable to evaluate the adequacy of your corrective action because you have not provided documentation that you have prepared and followed a written MMR that includes all required elements.

4. Your batch production record (BPR) failed to include complete information relating to the production and control of each batch, as required by 21 CFR 111.255(b) and 111.260. Specifically, none of the ten batch records we reviewed included complete information for the production and control of the batch. For example, The Green Herb brand Nu-Woman, batches 1822, 1780, and 1707; The Green Herb brand Vir-L-IV, batch 1538; **(b)(4)** brand **(b)(4)**, batches **(b)(4)**; **(b)(4)** Capsule, batches **(b)(4)**; and The Green Herb brand Nu-Man Plus, batch 1873 did not include the following required information:

- The identity of equipment and processing lines used in producing the batch [21 CFR 111.260(b)];
- The date and time of the maintenance, cleaning, and sanitizing of equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained [21 CFR 111.260(c)];
- A statement of actual yield and percentage of theoretical yield at appropriate phases of processing [21 CFR 111.260(f)];
- Documentation, at the time of performance, of packaging and labeling operations, including the unique identifier assigned to packaging and labels used and quantity used [21 CFR 111.260(k)(1)];
- Documentation, at the time of performance, of packaging and labeling operations, the results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results [21 CFR 111.260(k)(3)].

We have reviewed your response received on March 28, 2017. Your response states that you have included all necessary elements in your BPR, except for a statement of actual yield and percentage of theoretical yield. You also state you have no idea how to do this and fail to see the value in doing this suggestion. We are unable to evaluate the adequacy of your corrective action because you have not provided revised documentation which includes complete information relating to the production and control of each batch.

5. Your firm failed to collect and hold reserve samples of each lot of packaged and labeled dietary supplement that you distribute, as required by 21 CFR 111.83(a). For example, you did not collect and hold reserve samples for the dietary supplement product lots you manufacture and distribute, including, but not limited to:

- The Green Herb brand Nu-Woman, batch 1822, 1707, and 1708
- The Green Herb brand Vir-L-IV, batch 1538
- **(b)(4)** brand **(b)(4)**, batch **(b)(4)**

- **(b)(4)** Capsule, batch **(b)(4)**
- The Green Herb brand Nu-Man Plus, batch 1873

We have reviewed your response received on March 28, 2017. You state that you "began saving samples of every batch beginning March 1, 2017." We are unable to evaluate the adequacy of your corrective action because you have not provided written documentation of your procedures or other records that demonstrate that you are fulfilling all the requirements of 21 CFR 111.83 for reserve samples.

6. Your firm failed to establish and follow written procedures for holding and distributing operations, as required by 21 CFR 111.453. Specifically, you do not have written procedures for your holding and distributing operations.

We have reviewed your response received on March 28, 2017. We are unable to evaluate the adequacy of your corrective action because you have provided no documentation of your written procedures for our review.

7. Your firm failed to establish and follow written procedures for packaging and labeling operations, as required by 21 CFR 111.403. Specifically, you do not have written procedures for your packaging and labeling operations. Such procedures must satisfy the requirements that apply to packaging and labels as specified in 21 CFR 111.410, including:

a. You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies [21 CFR 111.410(b)];
b. You must examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record [21 CFR 111.410(c)];
c. You must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution [21 CFR 111.410(d)].

We have reviewed your response received on March 28, 2017. We are unable to evaluate the adequacy of your corrective action because you have not provided any documentation of your written procedures for our review.

8. You failed to make and keep documentation of personnel training, including the date of the training, the type of training, and the person(s) trained, as required by 21 CFR 111.14(b)(2). Specifically, you have no records related to employee training.

9. Your firm failed to establish and follow written procedures to fulfill the requirements related to returned dietary supplements, as required by 21 CFR 111.503. Specifically, you have no written procedures for returned dietary supplements.

10. Your firm failed to establish and follow written procedures to fulfill the requirements related to product complaints, as required by 21 CFR 111.553. Specifically, you have no written procedures for handling product complaints.

11. Your firm failed to establish and follow written procedures for cleaning the physical plant and for pest control, as required by 21 CFR 111.16. Specifically, you have no written procedures for cleaning the physical plant and for pest control. Once you have established such procedures, you must make and keep records of the written procedures for cleaning the physical plant and for pest control, as required by 21 CFR 111.23(b).

12. You failed to establish and follow written procedures for fulfilling the requirements related to equipment and utensils, as required by 21 CFR 111.25, including written procedures for (a) calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement; (b) calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and (c) maintaining, cleaning, and sanitizing, as necessary, all

equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements. Specifically, you have no written procedures for equipment and utensils.

Misbranded Dietary Supplements

The dietary supplement products discussed below are misbranded within the meaning of section 403 [21 U.S.C. § 343] of the Act and/or fail to comply with the regulations implementing the food labeling requirements of the Act, which are found in 21 CFR Part 101. Additionally, while, as noted previously, certain of your products are not labeled as dietary supplements, and therefore do not meet the definition of a dietary supplement (*see* section 201(ff)(2)(C) of the Act [21 U.S.C. § 321(ff)(2)(C)], it appears you may intend to market your Nu-Woman, Nu Man Plus, and Vir-L IV products as dietary supplements. Even if these products were dietary supplements and/or were not unapproved new drugs/misbranded drugs, they would be misbranded within the meaning of section 403 of the Act and/or in violation of the following provisions of 21 CFR Part 101.

1. Your Nu Man Plus, Nu-Woman, and Vir-L IV products are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] in that the labels fail to identify the products by using the term “dietary supplement” as a part of the product’s statement of identity, as required by 21 CFR 101.3(g).

2. Your Nu Man Plus, Nu-Woman, and Vir-L IV products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. § 343 (q)(5)(F)] in that the presentation of the nutrition information on the labeling of your products does not comply with 21 CFR 101.36. Specifically, your Nu Man Plus, Nu-Woman, and Vir-L IV product labels fail to present nutrition information in the form of a “Supplement Facts” panel, as required by 21 CFR 101.36.

Further, the **(b)(4)** Capsule and **(b)(4)** products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. § 343(q)(5)(F)] in that the presentation of the nutrition information on the labeling of these products does not comply with 21 CFR 101.36. Specifically:

- The **(b)(4)** Capsule and **(b)(4)** products declare vitamin B3 and vitamin B5 which is not the nomenclature or synonym specified for niacin and pantothenic acid in accordance with 21 CFR 101.9 or 101.36(b)(2)(i)(B).
- The **(b)(4)** Capsule and **(b)(4)** products fail to present the dietary ingredients in the correct order within the nutrition information in accordance with 21 CFR 101.36(b)(2)(i)(B).
- The **(b)(4)** product fails to declare any %DVs for declared dietary ingredients for which DRVs or RDIs have been established, in accordance with 21 CFR 101.36(b)(2)(iii).
- The **(b)(4)** product does not otherwise comply with the formatting requirements in accordance with 21 CFR 101.36(e).
- The **(b)(4)** product label fails to list the common or usual name of the source of the dietary ingredients, vitamin B1, vitamin C, **(b)(4)**, in accordance with 21 CFR 101.36(d)(1).

3. Your Nu Man Plus, **(b)(4)** Capsule, and Vir-L IV products are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)], in that the labels fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 CFR 101.4(h)(1).

4. The **(b)(4)** Capsule product is misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that the label fails to bear a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.

5. Your Nu-Woman, Nu Man Plus, and Vir-L IV products are misbranded within the meaning of section 403(i)(2) [21 U.S.C. § 343(i)(2)] of the Act in that the products are contained in capsules, but the capsule ingredients are not listed on the labels, as required by 21 CFR 101.4(g).

Further, the **(b)(4)** Capsule product is misbranded within the meaning of section 403(i)(2) [21 U.S.C. § 343(i)(2)] of the Act in that the label incorrectly lists “other ingredients” within the Supplement Facts panel. Other ingredients must be listed immediately below or immediately contiguous and to the right of the Supplement Facts panel, in accordance with 21 CFR 101.4(g).

Further, the **(b)(4)** product is misbranded within the meaning of section 403(i)(2) [21 U.S.C. § 343(i)(2)] of the Act in that the label fails to declare all the common or usual names of each ingredient used as required by 21 CFR 101.36 and 21 CFR 101.4. Specifically, the label declares the dietary ingredient **(b)(4)**, but this is not the common or usual name for the dietary ingredient.

6. Your Nu-Woman, Nu Man Plus, and Vir-L IV products are misbranded within the meaning of sections 403(q)(1)(B) [21 U.S.C. § 343(q)(1)B] and 403(q)(5)(F) of the Act [21 U.S.C. § 343 (q)(5)(F)] because the labels fail to declare the number of servings per container, in accordance with 21 CFR 101.36(b)(1)(ii).

7. Your Nu-Woman, Nu Man Plus, and Vir-L IV products are misbranded within the meaning of section 403(s)(2)(A)(ii)(I) of the Act [21 U.S.C. § 343 (s)(2)(A)(ii)(I)] in that each label fails to include the quantitative amount by weight per serving size of all the dietary ingredients as required by 21 CFR 101.36.

8. The **(b)(4)** product is misbranded within the meaning of sections 403(q)(1)(A) [21 U.S.C. § 343 (q)(1)(A)] and 403(q)(5)(F) [21 U.S.C. § 343(q)(5)(F)] of the Act in that the nutrition information does not provide the subheading “serving size”. The term “**(b)(4)** capsules provide”, which appears to be the serving size declared on the label, is incorrect. Serving size for a dietary supplement is the maximum amount consumed per eating occasion as recommended on the product label as defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2. Specifically, the product label suggests consumers take **(b)(4)** capsules **(b)(4)**, but the nutrition information is based on **(b)(4)** capsules which is the “per day” basis. The serving size should be listed as **(b)(4)** capsules. The listing of “per day” information is optional, but if provided on the label, must be in accordance with 21 CFR 101.36(e)(9)(ii). Additionally, because the serving size is not correctly declared, all nutrition information is also incorrect.

9. The **(b)(4)** product is misbranded within the meaning of section 403(f) of the Act [21 U.S.C. § 343(f)] because the product contains iron, but the labeling fails to bear the following warning statement required under 21 CFR 101.17(e): “WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.”

10. The **(b)(4)** Capsule product label is misbranded within the meaning of section 403(e)(1) of the Act [21 U.S.C. § 343(e)(1)] in that it fails to list the name and place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5.

11. The **(b)(4)** product is misbranded within the meaning of section 403(w) of the Act [21 U.S.C. § 343(w)] because the label contains a major food allergen, fish, but fails to identify the species of fish from which the fish liver oil is derived.

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility or 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 ensure that your firm complies with all requirements of federal law, including FDA regulations. You should take prompt action to correct or implement corrections to the violations cited in this letter. Failure to do so may result in legal action without further notice, including, without limitation, seizure and/or injunction.