Formulife, Inc. 5/12/17

Dallas District Office
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

May 12, 2017

2017-DAL-WL-21

WARNING LETTER

UPS Overnight

Brandon M. Smith, Owner and President
Formulife, Inc.
Purus Labs, Inc.
1253 Andrews Parkway
Allen, Texas 75002-2692

Dear Mr. Smith:

From July 12 through July 22, 2016, the U.S. Food and Drug Administration (FDA) inspected your dietary supplement facility located at 11370 Pagemill Road, Dallas, Texas, where your firm manufactures dietary supplements. During this inspection, our investigators found a number of violations of the current Good Manufacturing Practice (cGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulations, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). These violations cause the dietary supplements manufactured at your firm to be adulterated within the meaning of Section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under insanitary conditions that do not meet cGMP regulations for dietary supplements.

In addition, we have reviewed your Purus Labs, Inc. website at www.puruslabs.net. Based on our review, we have concluded that your Organ Shield product is in violation of Sections 505(a) and 502(f)(1) of the Act [21 U.S.C. §§ 355(a) and 352(f)(1)].

We have also reviewed the product labels for your Noxygen, Creagyn, Condense, **(b)(4)**, and D-Pol products. Based on our review, we have concluded that these products are misbranded within the meaning of section 403 of the Act [21 U.S.C. § 343].

You can find the Act and FDA regulations through links in FDA's website at **www.fda.gov (http://www.fda.gov/)**.

Unapproved New Drug

This is to advise you that FDA reviewed your website at the Internet address www.puruslabs.net in January 2017 and has determined that you take orders there for the product Organ Shield.

The claims on your website establish that the product is a drug under Section 201 (g)(1)(B) of the Act [21 U.S.C. § 321 (g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this

product for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your Organ Shield product is intended for use as a drug include:

- "silymarin [an ingredient in the product] … is comprised of several flavonolignands that help repair liver cells damaged by toxins…"
- "Beta-Sitosterol [an ingredient in the product]…has been shown in clinical settings to lower cholesterol and has been used to treat hypercholesterolemia."
- "Beta-Sitosterol [an ingredient in the product] has also been used in many studies in treating BPH (benign prostatic hypertrophy)."

Your Organ Shield product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a new drug as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. 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 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that 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 Organ Shield product is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your Organ Shield product fails to bear adequate directions for its intended use and, therefore, the product is 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 drug violates section 301(a) of the Act [21 U.S.C. § 331(a)].

Adulterated Dietary Supplements

Your **(b)(4)**, D-Pol, Condense Crisp Apple, and Noxygen dietary supplements are adulterated under section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] as are other dietary supplement products that you manufacture, 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, 21 CFR Part 111.

The inspection revealed the following significant violations of the CGMP requirements for dietary supplements:

1. You failed to conduct at least one appropriate test or examination to verify the identity of a component that is a dietary ingredient, prior to its use, as required by 21 CFR 111.75(a)(1)(i). Specifically, you failed to conduct identity testing on **(b)(4)**, used in the manufacture of **(b)(4)**, lot number **(b)(4)**, which was approved by your quality control on July, 11, 2016. You also failed to conduct identity testing on Vitamins D3, B6, B12, B9, Sodium Nitrate, and D Aspartic Acid, all of which were used in the manufacture of D-Pol Natural Hormone Amplifier, lot number 1100815, which was approved by your quality control personnel on May 16, 2016. Before using a component that is a dietary ingredient, you must conduct at least one appropriate test or examination to verify the identity of the dietary ingredient, unless you have petitioned FDA for an exemption from such testing, consistent with the requirements of 21 CFR 111.75(a)(1)(ii), and FDA exempts you from such testing. Your firm has not petitioned the FDA for such an exemption. This is a repeat violation from the 2014 and 2015 inspections of your firm.

We reviewed your written response, dated July 26, 2016. Your response states you received these ingredients prior to the implementation of your procedure, Sampling, Testing, and Release of Raw Materials, Number 002.13, effective date February 1, 2016. However, having received these dietary ingredients prior to the February 1, 2016, effective date of the SOP does not absolve your firm of the requirement to conduct identity testing of the dietary ingredients before their use in the manufacture of dietary supplements, including in May and July, 2016.

Your firm's adherence to the SOP, "Sampling, Testing, and the Release of Raw Materials," will be verified during the next inspection.

2. You failed to establish component specifications that are necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met, as required by 21 CFR 111.70(b)(2). Also, you failed to establish component specifications for limits on those types of contamination that may adulterate or 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(b)(3).

Specifically, you do not have specifications for purity, strength, and composition for the following dietary ingredients that you use to manufacture **(b)(4)**. For example, your **(b)(4)** Raw Material Specification Sheet lists only "Appearance" and "**(b)(4)**;" this specification does

not ensure the purity, strength, or composition of **(b)(4)**, an ingredient sourced from **(b)(4)**. This is a repeat observation from the 2014 and 2015 inspections of your firm.

We have reviewed your written response, dated July 26, 2016, and determined your response to be inadequate. Your response states you revised the Raw Material Specification sheets and you provided examples for the dietary ingredients **(b)(4)**, dated 7/23/16, as well as **(b)(4)** and **(b)(4)**, which are dated 7/22/16. However, these three raw material specifications do not address strength, purity, or limits for contaminants such as pesticides, heavy metals, or microbiological contaminants.

3. You failed to establish product specifications for the purity, strength, and composition of the finished batch of dietary supplement, and for limits on those types of contamination that may adulterate, or lead to the adulteration of, the finished batch of dietary supplement, as required by 21 CFR 111.70(e). Specifically, you have not established finished product specifications for purity, strength, and composition, or limits on contamination, for dietary supplements you manufacture, including **(b)(4)**, D-Pol, Condense Crisp Apple, and Noxygen dietary supplement products.

Your finished product specifications for **(b)(4)** dietary supplement do not include specifications for purity, strength, and composition of the finished batch of dietary supplement, and for limits on those types of contamination that may adulterate, or lead to the adulteration of, the finished batch of dietary supplement, including contaminants that may be contributed to the product from its herbal ingredients, such as **(b)(4)**.

Your finished product specifications for D-Pol, Condense Crisp Apple, and Noxygen list "**(b)(4)**" as the Target Value for *E. coli*, *Salmonella*, and *S. Aureus*, without defining "**(b)(4)**." Further, the specifications list a maximum value of "**(b)(4)**" for Total Plate Count, without specifying the size of the sample (e.g., per gram or other weight or volume unit). The D-Pol specification also lists "**(b)(4)**" Target Values of "**(b)(4)**," without a definition for "**(b)(4)**."

We have reviewed your written response, dated July 26, 2016, and determined your response to be inadequate. Your response states you will complete a "**(b)(4)**" on **(b)(4)**, and **(b)(4)** thereafter. However, you did not provide updated finished product specifications that demonstrate that you have established product specifications for purity, strength, composition, and limits on contamination. Once you have established these specifications, you must verify that your finished batch of the dietary supplement meets product specifications, as required by 21 CFR 111.75(c).

4. You failed to establish and follow laboratory control processes that are reviewed and approved by quality control personnel, including the use of criteria for selecting standard reference materials used in performing tests and examinations, as required by 21 CFR 111.315(d). Specifically, in your response dated July 26, 2016, you propose to use **(b)(4)** lots as internal standards, when reference standards are not readily available for identity testing of dietary ingredients by **(b)(4)**

However, you failed to demonstrate that the non-compendia standards originating from **(b)(4)** lots were thoroughly characterized to ensure their identity, purity, quality, and strength. Non-compendia reference standard materials should be of the highest purity by reasonable effort and should be thoroughly characterized to ensure their identity, purity, quality, and strength. Once characterized, the official qualification documentation of these standards must be reviewed and approved by Quality Control prior to use, as required by 21 CFR 111.110(a).

5. Your firm failed to approve, and release from quarantine, all components and packaging before they were used, as required by 21 CFR 111.120(e). Specifically, your quality control personnel did not approve and release from quarantine all components, including dietary ingredients, capsules, and packaging before they were used in your dietary supplement products, including dietary ingredients, capsules, bottles, and lids used in Purus Labs D-Pol Natural Hormone Amplifier lots 1100815 or **(b)(4)** lots **(b)(4)** and **(b)(4)**. This is a repeat observation from the 2015 inspection.

We have reviewed your written response, dated July 26, 2016, and determined your response to be inadequate. In your response, you stated you received these components and packaging materials prior to the implementation of your procedure, Packaging Component Approval and Release, number 002.42, effective date February 1, 2016, and that you have been approving packaging components since April 2016. However, regardless of when you received these packaging materials and components, you used them in the manufacture of D-Pol Natural Hormone Amplifier, lot number 1100815, which was approved by your quality control personnel on May 16, 2016. This dietary supplement was manufactured after your procedure was implemented, and yet quality control approved it for release without approval of all components and packaging materials.

Having received these dietary ingredients prior to the February 1, 2016, effective date of the SOP does not absolve your firm of the requirement for quality release of components before their use in the manufacture of dietary supplements, including in May, 2016, when Purus Labs D-Pol Natural Hormone Amplifier lots 1100815 was manufactured. To date, your firm has not provided evidence of quality

release for **(b)(4)** dietary ingredient lots listed in the FDA 483, or for any of the capsule lots or packaging material lots listed in the FDA 483.

Your firm's continued adherence to the SOP, "Packaging and Component Approval and Release," will be verified during the next inspection.

Misbranded Dietary Supplements

Your Noxygen, Creagyn, Condense, **(b)(4)**, and D-Pol Custard Crème dietary supplement products are misbranded under section 403 of the Act [21 U.S.C. § 343] because their labels do not comply with FDA's labeling regulations under 21 CFR Part 101, as follows:

1. Your Noxygen and Creagyn products are misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343 (q)(1)(A)] because the serving size declared on the labels is incorrect. The 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. The directions of use state, "Add one to two servings to your preworkout beverage 15-30 minutes before training…." The serving size listed in the Supplement Facts is "Approximately 1 scoop," thus it appears that your usage directions recommend using up to two scoops per eating occasion. As such, the serving size should be two scoops. We recommend your usage directions clearly state the amount of product, in scoops, to use per eating occasion.
2. Your Condense, Creagyn, Noxygen, 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 your products does not comply with 21 CFR 101.36. For example:
    a. Your Condense product label declares chloride with an amount of < 2%DV. Any (b)(2)-dietary ingredient not present, or in amounts that can be declared as zero in 21 CFR 101.9(c), shall not be declared (e.g., amounts corresponding to less than 2 percent of the RDI for vitamins and minerals) in accordance with 21 CFR 101.36(b)(2)(i).
    b. Your Creagyn product label lists a quantitative amount for total carbohydrate and sugar alcohol and Condense product label lists a quantitative amount and %DV for potassium that are in the incorrect increments. [21 CFR 101.9(c) and 101.36(b)(2)].
    c. Your D-Pol Natural Hormone Amplifier and D-Pol Custard Creme product labels declare vitamin B-9 which is not the nomenclature or synonym specified for folate in 21 CFR 101.9 or 101.36(b)(2)(i)(B).
    d. Your Creagyn and Noxygen product labels fail to place a heavy bar after the last (b)(2)-dietary ingredient. [21 CFR 101.36(e)(6)].
    e. Your **(b)(4)** product label declares **(b)(4)**, whereas **(b)(4)** is not a synonym specified for **(b)(4)**. [21 CFR 101.36(b)(2)(i)(B)].
3. Your D-Pol Custard Creme, **(b)(4)**, and Noxygen products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 342(i)(2)] in that the product 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:
    a. Your D-Pol Custard Creme label lists "Nitratene" in the proprietary blend and does not include the common or usual name for this dietary ingredient.
    b. Your **(b)(4)** label lists "**(b)(4)**" which is not the common or usual name for this dietary ingredient.
4. Your **(b)(4)** product is misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the label fails 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).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. It is your responsibility to assure your establishment is in compliance with all requirements of the Act and federal regulations. You should take prompt measures to correct all violations described in this letter. Failure to take appropriate corrective actions may subject your firm and products to further actions, such as injunction or seizure.

Additionally, FDA has the following comments:

1. Your products fail to list required label statements in an adequate type size, as required by 21 CFR 101.3(d). In accordance with 21 CFR 101.3(d), the statement of identity must be presented in bold type on the principal display panel and shall be in a size that is reasonably related to the most prominent printed matter on such panel. On your Noxygen, Condense, D-Pol Natural Hormone Amplifier, D-Pol Custard Creme, and Creagyn product labels, your statement of identity "dietary supplement" is in a significantly smaller type size and prominence on your labels than are the terms, "Muscle," "Instantly," "Hydromax," " Boom," "Nitric Oxide," "Original," "Potentiating," and other terms.

2. Your Creagyn product labels include a column for % Daily Value and note "* Daily Value (DV) not established" but do not include any notion of a percent or an "*" to designate that the Daily Value has not been established for the dietary ingredient. Your D-Pol Natural Hormone Amplifier product label uses a different symbol in the %DV column (**) than the symbol on the footnote (*).
3. Your Condense, **(b)(4)**, D-Pol Natural Hormone Amplifier, and D-Pol Custard Creme product labels bear the following or similar statement: "Percent Daily Values based on a 2,000 calorie diet" or "Daily Value based on 2,000 calorie diet." This statement is only permitted when the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, as required by 21 CFR 101.9(c) and 21 CFR 101.36(b)(2)(iii)(D).
4. Your **(b)(4)** product label lists non-dietary ingredients within the Supplement Facts. These "Ingredients" should be listed outside and directly below the Supplement Facts in accordance with 21 CFR 101.4(g).
5. Your Noxygen, Condense and D-Pol Natural Hormone Amplifier's Supplement Facts label includes the statement, "FCC grade." The ingredient statement for proprietary blends may not include such intervening material, as required by 21 CFR 101.2(e).
6. Your Noxygen product label's principal display panel bears the statement, "with Hydromax® glycerol," whereas the Supplement Facts label declares, "Hydromax® glycerine." We suggest using a consistent term when referring to the common or usual name for Hydromax® on the label in order to avoid confusion.

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 determine 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.

You should notify this office in writing within fifteen (15) business days from your receipt of this letter, of the specific steps you have taken to correct the noted deviations, including an explanation of each step taken to prevent their recurrence. In your response, include documentation of your corrective actions, including an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documents. If you cannot complete all corrective actions before you respond, we expect that you will explain the reason for your delay and state when you will correct the remaining deficiencies.

Your written response should be sent to Jamie M. Bumpas, Compliance Officer, U.S. Food and Drug Administration, 4040 North Central Expressway, Suite 300, Dallas, TX 75204. If you have questions regarding any issues in this letter, please contact Ms. Bumpas at 214-253-5336.

Sincerely,
/S/
Shari J. Shambaugh
Acting Dallas District Director

CC: Mr. Greg Wilburn
Inspection Unit Manager
Food and Drug Inspections Branch
1100 West 49th Street
Austin, Texas 78756

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