Total Nutrition Inc 8/16/17

U.S. FOOD & DRUG ADMINISTRATION

Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

WARNING LETTER
CMS # 525508

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

August 16, 2017

Mr. Jay M. Silverman, President
Total Nutrition, Inc.
75 Bi-County Boulevard
Farmingdale, NY 11735

Dear Mr. Silverman:

From March 6, 2017, through April 24, 2017, the U.S. Food and Drug Administration (FDA) inspected your facility located at 75 Bi-County Boulevard Farmingdale, NY 11735. During the inspection, our investigators identified significant violations of the Current Good Manufacturing Practice (CGMP) regulations for dietary supplements, Title 21 Code of Federal Regulations, Part 111 (21 CFR Part 111). These violations cause the dietary supplements manufactured at your facility 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 the dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements. Our investigators' observations were noted on form FDA-483, Inspectional Observations, which was issued to you on April 24, 2017. We received your firm's FDA-483 response correspondence, dated May 1, 2017. We provide comments to your response immediately following the violations addressed below.

Additionally, we reviewed your websites at the internet addresses www.tnvitamins.com and www.doctorspride.com on June 29, 2017, and we have determined that you take orders there for the products Aller Ease, Inflam Ease, Airway Clear, Osteo-Gest, Arth-Support, Olive Leaf Extract, Astragalus Root, Elderberry Sambucus, Tart Cherry, Tumeric Curcumin, Napro-Zyn With Tumeric, and Bromelain, and Boswellia. We have also reviewed your product

labels. The claims on your websites and/or product labels establish that the products are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You may find the Act and the FDA's regulations through links on FDA's home page at **www.fda.gov. (http://www.fda.gov/)**

Your significant violations are as follows:

Unapproved New Drugs/Misbranded Drugs

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

Aller Ease

(Website)

- "[A]ntihistimines"
- "Quercetin: Natural antihistamine"
- "Bromelain: Natural anti-inflammatory for sinus relief"
- "Nettle Root: Herb traditionally used for treatment of hay fever & other allergies."

(Product Label)

- "Nature's Allergy Relief Formula"

Inflam Ease

(Website)

- "Provides the Most Effective Natural Ingredients to Promote Healing from Minor Sprains and Injury"
- "Potent Relief Of Pain From Inflammation"

(Product Label)

- "Natural Anti-Inflammatory"
- "Inflam-Ease works synergistically to naturally relieve pain & swelling due to inflammation."

Airway Clear

(Website)

- "Herbal Combination Provides Quick Temporary Relief of Shortness Of Breath, Tightness Of Chest And Wheezing Due To Bronchial Asthma"

Osteo-Gest

(Product Label)

- "Osteo-Gest is a state-of-the-art, bone-building osteoporosis support formula…"

Arth-Support

(Product Label)

- “Arth Support contains ingredients that are key structural components in cartilage and play important roles in the maintenance of joint cartilage where arthritis may be found.”

The following products are listed under this heading “Cold & Flu” :

- Olive Leaf Extract
- Astragalus Root
- Elderberry Sambucus

The following products are listed under this heading “Asthma Clear” :

- Aller Ease
- Airway Clear

The following products are listed under this heading “Inflammation & Pain Relief” :

- Tart Cherry
- Tumeric Curcumin
- Napro-Zyn With Tumeric, Bromelain, and Boswellia

Your Aller Ease, Inflam Ease, Airway Clear, Osteo-Gest, Arth-Support, Olive Leaf Extract, Astragalus Root, Elderberry Sambucus, Tart Cherry, Tumeric Curcumin, and Napro-Zyn With Tumeric, Bromelain, and Boswellia products are not generally recognized as safe and effective for the above referenced uses and therefore, these products are “new drugs” under 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 the FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 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.

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 Aller Ease and Airway Clear products are 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 these products safely for their intended purposes. Accordingly, your Aller Ease and Airway Clear products 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

Even if your Aller Ease, Inflam Ease, and Osteo-Gest products were not drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)], they would be adulterated dietary supplements 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 conditions that do not meet CGMP regulations for dietary supplements, based on the following significant violations:

1. You 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, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, your firm lacks written procedures for quality control operations including, but not limited to, written procedures for conducting a material review and making a disposition decision, and written procedures for approving for release, or rejecting, any packaged and labeled dietary supplement (including a repackaged or relabeled dietary supplement) for distribution.

We have received your response letter, dated May 1, 2017, which states that Total Nutrition is preparing an SOP for material review and disposition. We are unable to evaluate the adequacy of your corrective action because you provided no information regarding your written procedures. Additionally, your response states, “Total Nutrition will not receive finished bulk for holding, packaging and distribution without proper Certificate of Analysis and Contaminant testing required by CFR 111.75 accompanying that batch.” To that extent you implement such procedures, we note that the certificate of analysis (COA) received from **(b)(4)** for the bulk shipments of Green Energy tablets **(b)(4)** and Total Arth Support capsules **(b)(4)** and the COA received from **(b)(4)** for Inflam Ease capsules **(b)(4)** indicate strength “based on input,” such as personnel adding the ingredients to the batch of product, at the time of manufacturing, and was not based on conducting analytical testing of the finished product. We note that such certificates of analyses would not provide an appropriate basis upon which your quality control operations could approve the dietary supplement for distribution [21 CFR 111.127(h)] because such COAs do not verify, using appropriate tests or examinations, that the dietary supplement meets product specifications.

We also note that once you have established your quality control written procedures, you must implement quality control operations into your packaging, labeling, and holding operations, as required by 21 CFR 111.65; and you must implement a system of production and process controls to ensure the quality of the dietary supplements, as required by 21 CFR 111.55. The quality control personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.105. Furthermore, you must have documentation of the quality control personnel review and approval for release of any packaged and labeled dietary supplement for distribution, as required by 21 CFR 111.127(h) and 111.140(b)(2).

As a distributor that contracts with other manufacturers to manufacture, package, or label dietary supplements that your firm releases for distribution under your firm’s name, your firm has an obligation to know what and how manufacturing activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution [72 Fed. Reg. 34752, 34790 (Jun. 25, 2007)]. Your firm introduces or delivers, or causes the introduction or delivery, of the dietary supplement into interstate commerce in its final form for distribution to consumers. As such, your firm has an overarching and ultimate responsibility to ensure that all phases of the production of that product are in compliance with dietary supplement CGMP requirements.

Although your firm may contract out certain dietary supplement manufacturing operations, it cannot by the same token, contract out its ultimate responsibility to ensure that the dietary supplement it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP requirements (see United States v. Dotterweich, 320 U.S. 277, 284 (1983) (explaining that an offense can be committed under the Act by anyone who has a “responsible share in the furtherance of the transaction which the statute outlaws”); United States v. Park, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that “agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act” can be held accountable for violations of the Act). In particular, the Act prohibits a person from introducing or delivering for

introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is adulterated under section 402(g) for failure to comply with dietary supplement CGMP requirements (see 21 U.S.C. §§ 342(g), 331(a)). Thus a firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations for it is responsible for ensuring that the dietary supplement is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations.

2. Your batch production records (BPRs) failed to include complete information relating to the production and control of each batch, as required by 21 CFR 111.255(b) and 21 CFR 111.260.

Specifically, your firm's Fill Worksheet and Packaging Check List that are used to document the packaging of finished dietary supplements into retail packaging for Aller Ease **(b)(4)**, Inflam-Ease **(b)(4)**, and Osteo-Gest **(b)(4)** fail to include the following:

- The identity of equipment and processing lines used in the producing the batch [21 CFR 111.260(b)];
- The date and time of maintenance, cleaning, and sanitizing of the 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)];
- Documentation that the finished dietary supplement meets specifications established in accordance with 21 CFR 111.70(g) [21 CFR 111.260(i)];
- Documentation, at the time of performance, of packaging and labeling operations, including:
    - The quantity of the packaging and labels used [21 CFR 111.260(k)(1)];
    - The results of any tests or examination conducted on packaged and labeled dietary supplements or a cross-reference to the physical location of such results [21 CFR 111.260(k)(3)].
- Documentation, at the time of performance that quality control personnel:
    - Reviewed the batch production record [21 CFR 111.260(l)(1)];
    - Approved or rejected any reprocessing or repackaging [21 CFR 111.260(l)(2)];
    - Approved and released, or rejected, the batch for distribution [21 CFR 111.260(l)(3)];
    - Approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement [21 CFR 111.260(l)(4)].

We have received your response letter, dated May 1, 2017; however, we are unable to evaluate the sufficiency of your corrective action. Your response states that you are amending all packaging records to address this violation, but you did not provide revised production batch records to document any corrective actions that you may be implementing.

3. You failed to establish and follow written procedures to fulfill the requirements related to returned dietary supplements, as required by 21 CFR 111.503. Specifically, your firm does not have written procedures regarding the handling of returned dietary supplements. In accordance with 21 CFR 111.510, you must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision. Additionally, you must make and keep records of any material review and disposition decisions on a returned dietary supplement, as required by 21 CFR 111.535(b)(2).

We have received your response letter, dated May 1, 2017; however, we are unable to evaluate the sufficiency of your corrective action. We acknowledge your response includes proposed corrective actions including the proposed creation of an SOP for returned dietary supplements; however you did not provide a copy of your SOP for implementation of the proposed corrective actions.

4. You failed to have a qualified person review and investigate all product complaints, as required by 21 CFR 111.560(a). Specifically, you have received product complaints, but your records do not demonstrate that a qualified person reviewed and investigated the complaints. Quality control personnel must review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed, as required by 21 CFR 111.560(b). The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, must extend to all relevant batches and records, as required by 21 CFR 560(c).

Your response letter, dated May 1, 2017 does not include any proposed corrective actions addressing this violation.

Misbranded Dietary Supplements

1. Your Osteo-Gest and **(b)(4)** Inflam-Ease products are misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that the labels fail to bear a current domestic address or domestic phone number through which the responsible person as described in section 761(b) of the Act [21 U.S.C. § 379aa-1(b)], may receive a report of a serious adverse event associated with the products.

2. Your Green Energy 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 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).

3. Your Arth-Support product is 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 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. The directions of use suggest the consumer take two (2) or more capsules daily, but the serving size lists 2 capsules. The serving size listed should be the maximum amount of capsules per eating occasion daily; furthermore, the directions, if noted, should be consistent with the serving size.

4. Your Aller-Ease, Osteo-Gest, and Arth-Support products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. 343 § 343(q)(5)(F)] in that the presentation of the nutrition information (“Supplement Facts” panel) on the labels of your product does not comply with 21 CFR 101.36. For example:

a. Your Aller-Ease, Osteo-Gest, and Arth-Support product labels list some (b)(2)- and (b)(3)- dietary ingredients in an incorrect order and/or not in accordance with the common or usual names in accordance with 21 CFR 101.36 and 21 CFR 101.9(c). For example, the names Vitamin D-3, Vitamin K-1, GLA, Glucosamine Sulfate 2KCL are not common or usual names of (b)(2)- or (b)(3)-dietary ingredients.

b. Your Aller-Ease and Osteo-Gest product labels list Opti-Zinc and MCH-Cal™ Microcrystalline Hydroxyapatite, respectively, and these are not the common or usual names of ingredients. Source ingredients of dietary ingredients must be listed by their common or usual name, either in the Supplement Facts panel or in the ingredient list. Furthermore, the “MCH-Cal™ Microcrystalline Hydroxyapatite” is listed as a dietary ingredient and as a source ingredient for several dietary ingredients. The listing of the source ingredient should be in accordance with 21 CFR 101.36(d).

c. Your Aller-Ease and Osteo-Gest product labels fail to separate the (b)(2)- and (b)(3)-dietary ingredients with a heavy bar in accordance with 21 CFR 101.36(e)(6).

d. Under 21 CFR 101.36(b)(2)(iii), the percent of the daily value must be declared for all dietary ingredients for which FDA has established daily values. Specifically, your Aller- Ease product label lists an incorrect percentage DV for the quantitative amount of Vitamin E listed based on the established referenced daily intake (RDI). The RDI's for each of the dietary ingredients can be found in 21 CPR 101.9(c)(8)(iv).

e. Your Osteo-Gest product label incorrectly lists the source ingredients for magnesium. When two or more source ingredients are used to provide a single dietary ingredient, all of the sources shall be listed in descending order by weight within the parentheses immediately following or indented beneath the name of the dietary ingredient and preceded by the words “as” or “from”, in accordance with 21 CFR 101.36(d).

f. Your Aller-Ease product label lists nettle (root). Your **(b)(4)** Inflam-Ease and **(b)(4)** Inflam-Ease product labels each list boswellia. Each of these names is not a standardized common name noted in Herbs of Commerce. The common or usual names of botanicals must be consistent with the names standardized in Herbs of Commerce (21 CFR 101.4(h)).

We offer you the following labeling comments:

- Your Arth-Support product label appears to give highlighting to specific (b)(2)- and (b)(3)-dietary ingredients through the use of increased bolding of the letters. Per 21 CFR 101.36(e)(1) only the title and all headings within the Supplement Facts panel are bolded to distinguish them from other information.
- For each of your products, a footnote pertaining to the DV is incorrectly stated; the footnote (if required) should read “Daily Value (DV) not established.”
- Your Arth-Support product declares beta-carotene. When beta-carotene is declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., “Vitamin A (100% as beta-carotene)).

This letter is not intended to be an all-inclusive list of violations in connection with your products or their labeling. 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 establishment and products comply with all applicable requirements of Federal law, including the Act and its implementing regulations. You should take prompt action to correct all violations noted in this letter. Failure to promptly correct these violations may result in enforcement action without further notice, such as seizure and/or injunction.

Section 743 of the FD&C Act (21 U.S.C. § 379j-31) authorizes FDA to assess and collect fees to cover FDA’s costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA’s arranging, conducting, and evaluating the results of the reinspection 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 reinspection-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 FD&C Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations and to prevent similar violations from occurring in the future. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.