WARNING LETTER

Market America Inc

MARCS-CMS 588959 — FEBRUARY 12, 2020

Product:

Dietary Supplements

Recipient:

Marc Ashley

COO/President

Market America Inc

1302 Pleasant Ridge Rd.
Greensboro, NC 27407-9415
United States

Issuing Office:

Office of Human and Animal Foods - East 3

United States

February 12, 2020

Reference: CMS # 588959

WARNING LETTER

Dear Mr. Ashley:

The United States (U.S.) Food and Drug Administration (FDA) conducted an inspection of your facility located at 1302 Pleasant Ridge Rd., Greensboro, North Carolina, from May 21, 2019, through May 28, 2019. Among other operations, your firm distributes dietary supplement products that are contract manufactured for you under your firm's name. The inspection found 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 homepage at www.fda.gov (/media/78552/download?attachment).

Failure to Submit a Serious Adverse Event Report

You failed to submit a Serious Adverse Event Report (SAER) as required by section 761(c) of the Act [21 U.S.C. § 379aa-1(c)]. Specifically, you received reports of the following serious adverse events but did not submit an SAER as required:

• Complaint dated 3/15/2018 - TLS Nutrition Shake. Complainant reported prolonged hospitalization due to becoming winded, vertigo symptoms, and inability to walk after using the product, for which complaint asserted six weeks of physical therapy were needed to regain the ability to walk.

• Complaint dated 1/28/2019 - TLS 21-Day Challenge Kit (TLS Nutrition Shakes, Isotonix OPC-3, NutriClean 7-DayCleansing System, TLS Core dietary supplement products). Complainant reported inpatient hospitalization was needed due to various adverse reactions including abdominal pain, constipation, vomiting, dizziness, itching of skin, weakness, shaking, insomnia, chills, headache, tingling and numbness, and cramps after a week of using the products.

Under section 761(c) of the Act, you must submit a report of a serious adverse event associated with any of your dietary supplements no later fifteen (15) business days after a report of the event is received through the address or phone number provided on your dietary supplement products.

Because prompt submission of such serious adverse event reports is important for public health reasons, the agency recommends that all serious adverse events be reported to FDA within fifteen (15) business days of receipt regardless of the means by which you receive the initial report. These serious adverse event reports should be submitted under the MedWatch Form 3500A. More information on adverse event reporting can be found on FDA's website at www.fda.gov (www.fda.gov), in the publication "Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection."

We acknowledge receipt of your written response dated July 11, 2019, to the observations reported to you on the Form FDA-483, Inspectional Observations, which was issued to you on May 28, 2019. With respect to the observations relating to serious adverse event reporting, you provided revised procedures for assessing the severity level of an adverse event and determining whether such event is reportable. While the revised procedures provide adequate details for assessing the severity of adverse events, your response does not address whether a retrospective review of all adverse events will be conducted to determine if a serious adverse event report should be submitted to FDA.

Misbranded Dietary Supplements

Your Isotonix OPC-3, Heart Health Essential Omega III, Isotonix Multivitamin, Isotonix Multivitamin with Iron, Isotonix OPC-3, and Isotonix Activated B-Complex products are misbranded dietary supplements under section 403 of the Act [21 U.S.C. § 343] because they do not comply with the labeling requirements for dietary supplements as required by 21 CFR 101, as follows:

1. Your Isotonix OPC-3 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 2 capfuls per 150 lbs of body weight for the first 7-10 days and take 1 capful thereafter, but the serving size lists 1 capful (3.3 g). The serving size listed should be 2 capfuls which is the maximum amount recommended.

2. Your Heart Health Essential Omega III, Isotonix Multivitamin, Isotonix Multivitamin with Iron, and Isotonix Activated B-Complex 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 does not comply with 21 CFR 101.36. For example:

• The Heart Health Essential Omega III and Isotonix Activated B-Complex product labels list (b)(2)-dietary ingredients in amounts that are zero or that can be declared as zero. Any (b)(2)-dietary ingredients not present, or in amounts that can be declared as zero in 101.9(c), shall not be declared in accordance with 21 CFR 101.36(b)(2)(i). Specifically:

o The Heart Health Essential Omega III label declares saturated fat, trans fat, total carbohydrates, and sugars

as zero.
o The Isotonix Activated B-Complex label declares calcium as “5 mg” (1 %DV); less than 2% DV is an amount that can be declared as zero in 101.9(c).

• The Isotonix Activated B-Complex label declares “thiamin HCL (vitamin B1),” “riboflavin-5-phosphate (vitamin B2),” and “niacinamide (vitamin B-3)”; the Isotonix Multivitamin and Isotonix Multivitamin with Iron labels declare “beta-carotene (vitamin A precursor).” The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words "as" or "from", in accordance with 21 CFR 101.36(d). The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient [21 CFR 101.36(b)(2)(ii)(A)]. “Vitamin B-3” is not a synonym specified for niacin in 21 CFR 101.9 or 101.36(b)(2)(i)(B).

3. Your Isotonix OPC-3 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. 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 the violations cited in this letter. Failure to correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

We also offer the following comments:

1. Your Isotonix Multivitamin and Isotonix Multivitamin with Iron product labels declare the quantitative amount of copper as 100 mcg whereas the correct unit of measurement is mg in accordance with 21 CFR 101.9(c)(8)(iv) and 101.36(b)(2)(ii)(B).

2. Your Isotonix Multivitamin and Isotonix Multivitamin with Iron product labels declare the ingredient “lo han” whereas the standardized common name listed in the reference Herbs of Commerce is “luo han guo.”

3. Your Isotonix OPC-3, Isotonix Multivitamin, and Isotonix Multivitamin with Iron product labels each include intervening material within the Supplement Facts label. The Isotonix OPC-3 label’s statement about Pycnogenol, the Isotonix Multivitamin label’s statement about Quatrefolic®, and the Isotonix Multivitamin with Iron label’s statements about Quatrefolic® and SunActive® Fe are not permitted within the Supplement Facts label. All information appearing on the information panel of the product label must appear in one place without other intervening material [21 CFR 101.2(e)].

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 do not believe that your products are in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your written response should be sent to Patricia F. Hudson, Compliance Officer, U.S. Food and Drug Administration, 60 8th Street, NE, Atlanta, GA 30309. If you have any questions regarding the content of this letter, please contact Patricia F. Hudson at 404-253-2221 or email at patricia.hudson@fda.hhs.gov.

Sincerely,
/S/

Ingrid A. Zambrana
District Director, FDA Atlanta District
Program Division Director
Office of Human and Animal Food Operations – East Division 3