Niche Pharmaceuticals, Inc 7/19/18

U.S. FOOD & DRUG ADMINISTRATION

Office of Human and Animal Food Operations
West Division 3
4040 North Central Expressway, Suite 300
Dallas, Texas 75204

July 19, 2018

CMS # 553911

WARNING LETTER

UPS Overnight

Mr. Stephen F. Brandon, Sr., Owner & CEO
Niche Pharmaceuticals, Inc.
580 Commerce Street, Suite 100
Southlake, Texas 76092-9156

Dear Mr. Brandon:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address https://magtabsr.com/ in May of 2018 and has determined that you take orders there for the product, Mag-Tab SR (magnesium L-lactate dihydrate). The claims on your website establish that the product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (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.

In addition, FDA reviewed your product label for Mag-Tab SR collected during an inspection of your facility at 580 Commerce Street, Suite 100, Southlake, Texas, on March 19-20 and March 22, 2018. Based on our review of your product label, we have determined that even if your Mag-Tab SR product did not bear claims rendering it a drug, it would be adulterated within the meaning of section 402(c) of the Act [U.S.C. § 342(c)] because it bears a non-permitted color additive.

As explained further below, introducing or delivering this product for introduction into interstate commerce violates the Act. You can find the Act and FDA regulations through links on the FDA's home page at **http://www.fda.gov (http://www.fda.gov/)**.

Unapproved New Drugs

Examples of some of the website claims that provide evidence that your Mag-Tab SR product is intended for use as a drug include:

Within the post on your website titled "Metabolic Health – Magnesium Deficiency and Metabolic Risk Factors" (https://magtabsr.com/metabolic-health-magnesium-deficiency-metabolic-risk-factors/):

- "Magnesium deficiency contributes to the underlying causes of metabolic syndrome. Choosing a highly absorbable magnesium supplement such as magnesium lactate is a health strategy to prevent metabolic syndrome."
- "Metabolic Syndrome, which sounds like a metabolism disorder, actually describes the presence of three or more of the following conditions:
- Increased blood pressure (greater than 130/85 mmHg)
- High blood sugar levels (insulin resistance and fasting blood sugar levels greater that 135)…

A diagnosis of metabolic syndrome places you at risk for developing heart disease stroke, obesity, and diabetes…"

Your website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of Mag-Tab SR for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

Within the Mag-Tab SR Benefits, testimonial section of your website, (https://matabsr.com/testimonials/):

- "My son has damage to his kidneys from chemotherapy. We tried all other magnesium supplements but could not get his blood level into the normal range… Since starting Mag SR, his blood levels are in the normal range…"
- "I use it to help keep my blood pressure normal…"

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" 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 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 product Mag-Tab SR 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, Mag-Tab SR 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 Supplement/Unapproved Color Additive

Even if your product labeling did not contain claims that render your product an unapproved new drug and misbranded drug, your Mag-Tab SR product would be adulterated under section 402(c) of the Act [U.S.C. 342(c)] because it contains a color additive which is unsafe within the meaning of section 721(a) of the Act. D&C Yellow No. 10 is not permitted for coloring foods, including dietary supplements. The introduction or delivery for introduction into interstate commerce of an adulterated food violates section 301(a) of the Act [21 U.S.C. 331(a)].

This letter is not an intended to be an all-inclusive list of violations in connection with your products. It is your responsibility to ensure that your establishment and your products comply with 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, including, without limitation, seizure and/or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations from occurring in the future. You should include in your response documentation and any other useful information that would assist us in evaluating your corrections. 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. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration.

Section 743 of the Act [21 U.S.C. 379j-31] authorizes FDA to assess and collect fees to cover the 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 Act, specifically to determine whether compliance has been achieved. Reinspection-related cost 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 reinspection 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 Act. Accordingly, the FDA may assess fees to cover any reinspection-related costs.

Your written response should be sent to Paul E. Frazier, 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 Mr. Frazier at 214-253-5340 or paul.frazier@fda.hhs.gov.

Sincerely,
/S/
Edmundo Garcia Jr. District Director
Program Division Director
Office of Human and Animal Food, WD3

Cc:
Lori Woznicki, Food and Drug Inspections Branch
Manager Division of Regulatory Services
Texas Department of State Health Services

1100 E. 49th Street – Mail Code 1987
Austin, Texas 78756

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