Focus Laboratories, Inc. 6/3/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

June 3, 2016

2016-DAL-WL-24

WARNING LETTER

UPS OVERNIGHT

Brad C. Winfrey
President and Chief Executive Officer
Focus Laboratories, Inc.
7645 Counts Massie Rd
North Little Rock, AR 72113-6656

Dear Mr. Winfrey:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.focuslaboratories.com and www.mytozal.com in February 2016, and has determined that you take orders for the product Tozal® Complete Eye Health Formula (Tozal®) on the www.focuslaboratories.com website, which links directly to your www.mytozal.com website; the content of which is considered labeling. The labeling claims on these websites represent this product as a medical food for age-related macular degeneration. Based on our review, we have determined that your Tozal® product is misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 343(a)(1)], because the labeling is false and misleading in that the product is labeled and marketed as a medical food but does not meet the statutory definition of a medical food in the Orphan Drug Act [21 U.S.C. § 360ee(b)(3)] or the criteria set forth in 21 CFR 101.9(j)(8). Furthermore, because the product labeling markets Tozal® as a medical food, although the product does not meet the statutory definition of a medical food,

FDA has determined that your product is promoted for conditions that cause it to be a drug under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)].

Additionally, in April 2016, the U.S. Food and Drug Administration (FDA) reviewed your website www.freshkote.com, which directly links to www.focuslaboratories.com. The labeling claims on these websites represent this product as a drug within the meaning of section 201(g)(1)(B) and (C) of the Act [21 U.S.C. § 321(g)(1)(B) and (C)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and intended to affect the structure or any function of the body of man or other animals. These websites promote FreshKote® as an Over-the-Counter (OTC) monograph human drug (NDC #15821-101). In order for FreshKote® to be marketed under the OTC monograph as Generally Recognized As Safe and Effective (GRAS/E) and not misbranded, it must meet all the requirements of the final monograph for Ophthalmic Drug Products for OTC Human Use, 21 CFR Part 349 and each of the general conditions established in 21 CFR 330.1. FreshKote® does not meet these requirements and conditions because it is indicated for uses that fall outside of or are not related to the acceptable indications. You can find the Act and FDA regulations through links at FDA's home page at **http://www.fda.gov (http://www.fda.gov/)**.

Misbranded Food – Tozal®

The Orphan Drug Act defines "medical food" as "a food which is formulated to be consumed or administered eternally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." The regulation in 21 CFR 101.9(j)(8) provides that a food is considered a medical food only if:

i. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube;

ii. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

iii. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

iv. It is intended to be used under medical supervision; and

v. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

FDA considers the statutory definition of "medical food" to narrowly constrain the types of products that fit within this category of food.[1] Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.[2]

Pursuant to 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. Your websites www.focuslaboratories.com and www.mytozal.com promote your Tozal® product as a medical food for use by persons with age related macular degeneration.

Because FDA is not aware of any distinctive nutritional requirements or unique nutrient needs for individuals with age related macular degeneration, your Tozal® product does not meet the regulatory criterion for medical foods set forth in 21 CFR 101.9(j)(8)(ii). Therefore, your Tozal® product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C § 343(a)(1)] because the product labeling is false and misleading in that the product labeling promotes the product as a medical food but the product does not meet the definition of a medical food.

Unapproved New Drug – Tozal®

In addition, because your Tozal® product labeling promotes the product as a medical food, but does not meet the statutory definition of a medical food, the claims on the related websites (www.focuslaboratories.com and www.mytozal.com) establish that the above-mentioned 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 product is intended for use as a drug are listed below. This list is not inclusive of all claims demonstrating the product's intended use.

From your website www.mytozal.com:

- "Age-Related Macular Degeneration (AMD) is the leading cause of blindness in people over the age of 60. Results of the TOZAL study showed that 76% of patients taking TOZAL for at least six months experienced improvement or stabilization of vision…"
- "TOZAL® is indicated for the distinct nutritional requirements of individuals diagnosed with, or at risk for, Age Related Macular Degeneration*…"
- "[F]or the Dietary Management of Age Related Macular Degeneration*…"
- "[T]reat age related macular degeneration…"
- "[T]o reduce the progression of AMD and its associated vision loss…"
- "[H]elp prevent cellular damage…"
- "[M]ay lower the risk of developing AMD…"
- "Proven to Improve or Stabilize Vision for AMD…"

- “[T]aking high levels of antioxidants and zinc can reduce the risk of developing advanced Age-Related Macular Degeneration (AMD) by about 25%. Omega-3 fatty acids (EPA/DHA) from fish oil reduces the risk of developing Dry AMD by 32%* and Wet AMD by 70%.**…”
- “[R]educed the progression of advanced AMD by 25%, and the risk of moderate vision loss by 19%...”
- “For the 57% of patients in the TOZAL® study they showed an increase in visual acuity within 6 months of starting the study. However, the goal of TOZAL® therapy is to stabilize and maintain vision and not all patients will notice visual improvements...”

From your website www.focuslaboratories.com:

- “Tozal®, a treatment for age-related macular degeneration (AMD)…”
- “[T]o…treat age related macular degeneration…”
- “[S]hown to reduce the progression of AMD and its associated vision loss…”
- “[T]o treat Dry Eye…”
- “[M]ay lower the risk of developing AMD…”

Unapproved New Drug – FreshKote®

The claims on your product’s website www.freshkote.com, which links directly to your www.focuslaboratories.com website, establish that FreshKote® 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 product is intended for use as a drug are listed below. This list is not inclusive of all claims demonstrating the product’s intended use.

From your website www.freshkote.com:

- “For optimal treatment, use FreshKote to … heal the damaged epithelium.”
- “FreshKote treats all three layers of the tear film, essential to effective dry eye treatment.”
- “The High Oncotic Pressure found in FreshKote (65mmHg) offsets the intra-ocular pressure. This helps to normalize the inward osmotic flow of the tears (from the ocular surface towards the cornea), keeping the tears on the ocular surface.”
- “The High Oncotic Pressure in FreshKote compresses the epithelium, helps to re-establish the integrity of the epithelium and also assists in removing excess water from the epithelium.”

Based on the above claims, FreshKote is a “drug” as defined by section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)], because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(C)] because it is intended to affect the structure or any function of the body of man. Specifically, this product is intended for uses that go beyond the labeled demulcent (lubricant eye drop) indications

listed on the FreshKote® product label. OTC ophthalmic drug products intended as demulcents, such as FreshKote, are subject to the Final Monograph for Ophthalmic Drug Products for OTC Use (see 21 CFR Part 349). However, this product is not labeled or formulated in accordance with this final monograph for the reasons explained below.

The product website for FreshKote® includes indications such as, “heal the damaged epithelium,” “treats all three layers of the tear film,” “offsets the intra-ocular pressure,” and “compresses the epithelium, helps to re-establish the integrity of the epithelium and also assists in removing excess water from the epithelium” that are not included under this rulemaking or any rulemaking being considered under the OTC Drug Review.

In addition, the formulation for FreshKote® is not consistent with the formulation requirements that describe acceptable active ingredients for demulcent drug products (see 21 CFR 349.12). Specifically, your product website presents the claim, “FreshKote utilizes Amisol®CLEAR which helps restore and replenish the lipid layer to stabilize the tear film and delay evaporation.” According to 21 CFR 201.66(b)(2), an “active ingredient” means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. Although your firm does not specifically list Amisol®CLEAR as an active ingredient, your website claim for this specific ingredient that is described above demonstrates that this is an “active ingredient” as defined in 201.66(b)(2) because the ingredient is intended to furnish pharmacological activity. Amisol®CLEAR is not recognized as a demulcent active ingredients in 21 CFR 349.12. Thus, as currently formulated and labeled, FreshKote® does not comply with the final monograph for OTC ophthalmic demulcent drug products.

Your products (Tozal® and FreshKote®) are not generally recognized as safe and effective for the above referenced uses and therefore, they 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)]. 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 uses. “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 products (Tozal® and FreshKote®) are each 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, these products fail 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)].

This letter may not be an all-inclusive review of your websites or the products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the requirements of the Act and all applicable regulations. Failure to promptly correct violations may

result in regulatory action being initiated by FDA without further notice, such as seizure and/or injunction.

Please respond in writing within 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. You should include in your response documentation such as revised labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Please submit your response to Chad Whitwell, Compliance Officer, at the above letterhead address. If you have any questions please contact Mr. Whitwell at (214) 253-5328.

Sincerely,
/S/
Reynaldo R. Rodriguez, Jr.
Dallas District Director

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[1] *See* Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision Proposed Rule (56 FR 60366 at 60377, Nov. 27, 1991) and *see also* Draft Guidance for Industry: Frequently Asked Questions About Medical Foods, August 2013.
[2] 56 FR 60366 at 60377.

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