WARNING LETTER

Earthworks Health

MARCS-CMS 560772 — 07/06/2019

Delivery Method:

VIA UNITED PARCEL SERVICE

Product:

Drugs
Food & Beverages

Recipient:

Mr. Larry D. Smith

Owner

Earthworks Health

2100 N. 13th St.
Norfolk, NE 68701
United States

Issuing Office:

Office of Human and Animal Food- West Division II

8050 Marshall Drive - Suite 205
Lenexa, KS 66214-1524
United States

June 7, 2019

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

CMS Case # 560772

Mr. Larry D. Smith, Owner
Earthworks Health, LLC
2100 N. 13th St.
Norfolk, NE 68701

Dear Mr. Smith:

This is to advise you that in April 2019 the Food and Drug Administration (FDA) reviewed your Facebook page, your YouTube channel, and your website at the Internet address www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), where you take orders for the products 100% Food Grade Diatomaceous Earth, Diatomaceous Earth Cosmetic Bundle, Goat Milk Soap with Food Grade Diatomaceous Earth, Nature's Face Mask, and Natural Dog Treats. Based on our review of your internet labeling described below, we have concluded that: (1) your 100% Food Grade Diatomaceous Earth, is in violation of Sections 505(a), 502(f)(1), and/or 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §§ 355(a), 352(f)(1), and/or 342(a)(2)(C)(i), respectively]; (2) your Goat Milk Soap with Food Grade Diatomaceous Earth, Diatomaceous Earth Cosmetic Bundle, and Nature's Face Mask products are in violation of Sections 505(a), 502(f)(1) the Act; and (3) your 100% Food Grade Diatomaceous Earth and Natural Dog Treats products are in violation of section 512(a) of the Act, [21 U.S.C. § 360b(a)], and section 501(a)(5) of the Act [21 U.S.C. § 351(a)(5)].

You may find the Act and FDA's regulations through links on FDA's homepage at www.fda.gov (http://www.fda.gov).

Unapproved New Human Drugs and Misbranded Human Drugs

The claims on your internet labeling establish that your 100% Food Grade Diatomaceous Earth product (DE) 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 include:

Your YouTube channel Earthworks Health, which lists the site www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where products can be purchased, has a video, "Earthworks Diatomaceous Earth," which contains the claims:

- "Internal De-Wormer"
- "Great for connective tissue disorders, pain, and sleep issues"
- "Removes Toxins From The Gut"
- "Removes a variety of Toxin [sic] From the Digestive Tract"

Your Facebook page Earthworks Health, which has links to www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where the products can be purchased, bears the claims:

- "Food grade diatomaceous earth users report that it absorbs metals, pesticides, fungus, and drug residues when ingested"

Your Facebook page also contains evidence of intended use in the form of personal testimonials recommending or describing the use of diatomaceous earth for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

- "I have been getting shots in my shoulders and knees for years. I was scheduled for both knees getting replaced. I am bone on bone. I took DE and felt results within an hour on my worst knee. I have been taking it since mid Jan and no longer get shots . . . I gave some to friends and family. they [sic] are . . . virtually pain

free”

□ “DE is an absolute life saving, pain relieving God send . . .”

Your DE 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 DE 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 DE 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)].

In addition, FDA reviewed your website at the Internet address www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and has determined that you take orders there for the products Diatomaceous Earth Cosmetic Bundle, Goat Milk Soap with Food Grade Diatomaceous Earth, and Nature’s Face Mask. The claims on your website establish that these products are drugs under section 201(g)(1)(B) and/or 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §§ 321(g)(1)(B) and/or 321(g)(1)(C)] because they are intended for use in the cure, mitigation, treatment or prevention of disease and/or are intended to affect the structure or function of the human body. Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:

Diatomaceous Earth Cosmetic Bundle
□ “[T]reating skin problems like blemishes…and acne”

Goat Milk Soap with Food Grade Diatomaceous Earth
□ “[C]ontrol acne”

Nature’s Face Mask
□ “Comfrey Root Powder [an ingredient in your product] (restructuring and pain relief from acne or cystic acne)”

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the 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 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.

Adulterated Human Food

Even if your DE product for human use was not an unapproved new drug, it would be adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)] in that it is a food additive that is unsafe within the meaning of Section 409 of the Act [21 U.S.C.§ 348].

If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive. Section 201(s) of the Act [21 U.S.C. § 321(s)] defines a food additive as a "substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use [(GRAS)]." ***1*** Food additives require premarket approval based on data demonstrating safety (see section 409 of the Act). Any food additive that has not been approved for its intended use in food is deemed to be unsafe and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act.

Your labeling provides evidence that your DE product is intended to become a component or otherwise affect the characteristics of any food. Specifically:

Your website www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), from which your diatomaceous earth products can be purchased, states:

- "Storing foods . . . For every 1 gallon of grains or stored foods please combine 1 level tablespoon with it. So as you fill your mylar lined 5 gallon bucket with wheat, be sure to dump in 1 level tablespoon every 1 gallon you pour into it."

- "So next time you start prepping your foods, be prepared with food grade diatomaceous earth and add some shelf life and NUTRITION to your stored foods for when the time is right!"

The use of diatomaceous earth for direct addition to food (which is your product's intended use) is not the subject of any food additive regulations in Title 21 of the Code of Federal Regulations (21 CFR) or Generally Recognized as Safe (GRAS) determinations.

DE is the subject of secondary direct or indirect food additive regulations that provide for the safe use of DE, including as: 1) a carrier for amyloglucosidase enzyme product (see 21 CFR 173.110); 2) a colorant for paper and paperboard (see 21 CFR 176.170); 3) a colorant for polymers (see 21 CFR 178.3297); and 4) an optional adjuvant in the production of phenolic resins (see 21 CFR 177.2410). DE is also the subject of threshold of regulation (TOR) exemption 2005□007 for use as a component of foam trays. GRAS uses for DE include: 1) as a substance migrating to food from paper and paperboard products (see 21 CFR 182.90); 2) as a carrier for lipase enzyme preparation (see 21 CFR 184.1420); and 3) it's use in food processing as a filtration aid as a component of composite filtration media is the subject of GRAS Notice 87, to which FDA had no questions.

However, FDA has not evaluated the safety of the use of DE for direct addition to food and we are not aware of an independent GRAS determination by qualified experts for this use of DE. Your firm's promoted use of DE does not conform with a food additive exemption or regulation established pursuant to Section 409 of the Act. As such, DE is adulterated under section 402(a)(2)(C)(i) of the Act. The introduction of an adulterated food into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

Unapproved New Animal Drugs

FDA also reviewed your website at www.earthworkshealth.com (http://www.earthworkshealth.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for your product 100% Diatomaceous Earth and Natural Dog Treats. The claims on your website establish these products are intended for use in the cure, mitigation, treatment, or prevention of diseases in animals, which makes them drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Further, as discussed below, these products are unapproved new animal drug and introducing or delivering this product for introduction into interstate commerce violates the Act.

Examples of some of the claims that provide evidence that your products are intended for use as animal drugs are identified below.

Diatomaceous Earth for Dogs:

Website https://www.earthworkshealth.com/diatomaceous-earth-for-dogs/ (https://www.earthworkshealth.com/diatomaceous-earth-for-dogs/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

□ "…many feel the presence is DE in the dog helps with parasite control and other toxins removed from the digestive tract…"

□ "Reported in scientific literature to absorb methyl mercury, e-coli, endotoxins, viruses, organophosphate pesticide residues, drug residues, and protein, perhaps even the proteinaceous toxins produced by some intestinal infections. Therefore reducing chances of intestinal disease."

□ "Reported in scientific literature to kill parasites like whip worms, roundworm, pin worm, and tapeworm."

□ "Reports of arthritic pain relief."

Natural Dog Treats:

Website: https://www.earthworkshealth.com/product/natural-dog-treats/ (https://www.earthworkshealth.com/product/natural-dog-treats/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

□ "Diatomaceous Earth, our main ingredient, is a natural health supplement and a parasite killer."

□ "Helps aid in parasite control"

Because your 100% Diatomaceous Earth and Natural Dog Treat products are intended to cure, mitigate, treat, or prevent diseases in animals, it is a drug within the meaning of section 201(g)(1)(B) of the Act, [21 U.S.C. § 321 (g)(1)(B)]. Moreover, they are new animal drugs, as defined by section 201(v) of the Act, [21 U.S.C. § 321(v)], because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. They are not the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing under sections 512, 571, and 572 of the Act [21 U.S.C. §§ 360b, 360ccc, and 360ccc-1]. Therefore, these products are

unsafe within the meaning of section 512(a) of the Act, [21 U.S.C. § 360b(a)], and adulterated under section 501(a)(5) of the Act [21 U.S.C. § 351(a)(5)]. The introduction or delivery for introduction into interstate commerce of these adulterated drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility or 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 your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt measures to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that 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 believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. 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.

Your written reply should be sent to Danial S. Hutchison, Compliance Officer, U.S. Food and Drug Administration, 8050 Marshall Dr., Suite 205, Lenexa, KS 66214. If you have any questions, please contact Compliance Officer Hutchison at 913-495-5154.

Sincerely,
/S/

Cheryl A. Bigham
Program Division Director
Office of Human and Animal Foods
Division II West

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1 Under section 201(s) of the FD&C Act [21 U.S.C. § 321(s)], the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a “prior sanction” (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act; (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.

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