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Jason Bagley <jbagley@truthinadvertising.org>

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1 message

Bonnie Patten <bonniepatten@gmail.com> Wed, Aug 13, 2014 at 9:45 AM
To: Jason Bagley <jbagley@truthinadvertising.org>

ad alert

Jason - do you think we can get up at least one of these a day?

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm408739.htm

Dr. Bronner's Magic Soaps 7/8/14

Department of Health and Human Services

Public Health Service

Food and Drug Administration

College Park, MD 20740

JUL 8, 2014

WARNING LETTER

VIA OVERNIGHT DELIVERY

David Bronner, CEO

Dr. Bronner's Magic Soaps

PO Box 28

Escondido, CA. 92029

Re: 422294

Dear Mr. Bronner:

This letter is to advise you that in January 2014, the Food and Drug Administration (FDA) reviewed the label for your product, Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil. Based on our review of the product label, we have determined that your product is promoted for conditions that cause it to be 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)]. The therapeutic claims on your label establish that the product is a drug 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.

Even if your Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil product was not an unapproved new drug, it would be a misbranded food under section 403 of the Act [21 U.S.C. § 343]. The introduction of a misbranded food into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

You can find the Act and FDA regulations through links in FDA's home page at http://www.fda.gov.

Unapproved New Drug

The following claim on your product label provides evidence that your product is intended for use as a drug:

- "Clinical research confirms that the saturated medium chain fatty acids (MCT's) in [Virgin Coconut Oil], such as lauric acid, actually improve blood cholesterol by increasing the ratio of HDL to LDL cholesterol."

This claim indicates that your Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil product is intended for use in mitigating, treating, or preventing the disease, coronary heart disease. Since high blood total- and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease, the claim that your product "improve(s) blood cholesterol by increasing the ratio of HDL to LDL" implies that your product is intended for use in the treatment, mitigation, and prevention of coronary heart disease.

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)(1) of the Act [21 U.S.C. § 321(p)(1)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in section 505(a) of the Act [21 U.S.C. § 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.

Furthermore, your Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended use. Thus, this drug is misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that its labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

A statement that characterizes the relationship between a food or food component in a product and reduced risk of a disease or health-related condition can in some situations be a health claim (see section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)]). We note that there are no health claims authorized by regulation or the Act that provide for claims relating coconut oil to coronary heart disease.

Food Labeling Violations

Our review of your labeling revealed the following significant misbranding violation:

Your Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil product is misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the label fails to include a declaration of *trans* fat as required by 21 CFR 101.9(c)(2)(ii).

The violations cited in this letter are not meant to be an all-inclusive list of violations that exist 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 firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including but not limited to seizure and/or injunction.

Within 15 days of receipt of this letter, please notify this office in writing of the specific steps you

have taken to correct the violations noted above. Include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the corrections.

You should direct your written reply to Carrie Lawlor, Division of Enforcement (HFS-608), Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions regarding this letter, you may contact Ms. Lawlor via e-mail at carrie.lawlor@fda.hhs.gov.

Sincerely,
/S/

William A. Correll, Jr.

Acting Director

Office of Compliance

Center for Food Safety

And Applied Nutrition

cc: FDA Los Angeles District