DISCLOSURE QUESTIONAIRE

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, litigation, or sensitive industry practices).

If the company answers affirmatively to any items in the Disclosure Questionnaire and chooses to pursue B Corp Certification, a company must also:

1) Be transparent about the sensitive issues identified on the company's public B Impact Report.
2) Describe how the company has addressed this issue.
3) Demonstrate that management systems are in place to avoid similar issues from arising in the future.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit of the community.

This document contains a copy of the company's completed Disclosure Questionnaire and related documentation provided by the company.

Certified B Corporation
bcorporation.net

DISCLOSURE QUESTIONAIRE

Company Name: Dr. Bronner's

Date Submitted: 9/23/2015

Industries & Products	Yes	No
Please indicate if the company is involved in production of or trade in any the following (check all that apply.)		
Any product or activity deemed illegal under host country laws or regulations		√
Alcohol (excluding beer and wine)		√
Commercial logging and logging equipment		√
Firearms, weapons or munitions		√
Genetically modified organisms		√
Mining		√
Nuclear Power		√
Fossil fuel-based oil or coal utility		√
Pornography		√
Tobacco		√
Wildlife or wildlife products regulated under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)		√

Penalties, Fines & Sanctions	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies (check all that apply.)		
Animal welfare		√
Diversity and equal opportunity		√
Employee safety or workplace conditions		√
Environmental issues		√
Financial reporting		√
Geographic operations or international affairs		√
Investments or Loans		
Labor issues (internal and supply chain)		√
Marketing	√	View More >>
Political contributions		√
Product safety		√
Taxes		√

Practices	True	False
Please indicate if the following statements are true regarding whether or not the company engages in the following practices (check all that apply.) If the statement is true, select "True." If false, select "False."		
Company is formally registered in accordance with domestic regulations	√	
Company has not reduced or minimized taxes through the use of corporate shells or structural means	√	
Company facilities are not located adjacent to or in sensitive ecosystems	√	
No animal testing conducted	√	
Company or company supplier does not employ workers under the age of 15 (or other minimum work age covered by the International Labour Organization Convention No. 138)	√	
Overtime work for hourly workers is voluntary (not compulsory)	√	
Company or company suppliers do not use any workers who are prisoners	√	
Company allows workers to freely associate and to bargain collectively for the terms of one's employment	√	

Outcomes	True	False
Please indicate if the following statements are true regarding if the company has experienced any of the following in the past 5 years (check all that apply.) If the statement is true, select "True." If false, select "False."		
Company and Significant Suppliers has not had an operational or on-the-job fatality	√	
Company and Significant Suppliers' sites have not experienced any accidental discharges to air, land or water of hazardous substances	√	
No construction nor operation of company facilities and Significant Suppliers' facilities have resulted in the relocation of any individuals or households near your facility	√	
No material litigation against company	√	
No material recalls due to quality control issues	√	

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: **Dr. Bronner's**

UPDATED AS OF: **09/23/2015**

CATEGORY	Marketing
ISSUE DATE	July 8, 2014
ISSUE DESCRIPTION	The FDA sent a warning letter regarding a reference on our virgin coconut oil label made to the health benefits of coconut oil, and to the omission of a trans fat content line in the nutrition facts panel even though there are no trans fats in the product.
SUMMARY OF ISSUE	The label formerly included the following truthful statement about what clinical research had shown about the beneficial effects of saturated medium chain fatty acids found in coconut oil: "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." The FDA warned that the statement could not be included on the label because it could indicate the product is intended for use as a drug, which it is not. The second point in the FDA letter was that although this product contains no trans fat, Dr. Bronner's should have disclosed that fact in the nutrition labeling box on the label per an update to FDA regulations.
RESOLUTION	At the time of the letter receipt (July 15, 2014), Dr. Bronner's had actually already removed the clinical research statement from product labels. But we promptly changed our labels to show zero trans fat in this product, updated our website, destroyed all remaining applicable label inventory and marketing materials, sent a response letter to the FDA explaining our immediate actions and compliance, and documented the incident on our website.
IMPLEMENTED MGT PRACTICES	The incident has been resolved and is documented on our website.
REPORT	View More >>
OTHER MANAGEMENT COMMENTS	FDA took no issue with a separate statement that "Extensive research in the tropics shows that people who follow a traditional diet high in coconut oil enjoy excellent cardiovascular health." However Dr. Bronner's chose to remove that statement as well.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Inspections, Compliance, Enforcement, and Criminal Investigations

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[1].

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 thes 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

Page Last Updated: 08/11/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. /default.htm

DR. BRONNER'S MAGIC "ALL-ONE!"

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tel: 760.743.2211 • fax: 760.745.6675
www.drbronner.com

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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
Email: carrie.lawlor@fda.hhs.gov

August 19, 2014

Re: 422294

Dear Ms. Lawlor:

This letter is in response to the Warning Letter (Re: 422294) we received on July 15, 2014 regarding the Food and Drug Administration (FDA) label review for our product, Dr. Bronner's Magic "All-One!" Fresh-Pressed Virgin Coconut Oil (coconut oil).

Per the instructions outlined in the Warning Letter, we would like to advise you of the specific steps we have promptly taken that address the violations noted:

1. **Violation Noted: 'Unapproved New Drug' claim (Section 403 of the Act [21 U.S.C. 343])**

   Dr. Bronner's Action Taken: Claim is now removed from all labels.

   In January, 2014, at the time of the label review, our labels indeed bore the claim, "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," but this is no longer true.

   In fact, we removed that phrase from all domestic labels printed on or after May 23, 2014, per a May, 21, 2014 meeting with Steve Damberger, Food & Drug Inspector from the California Department of Public Health Food & Drug Branch.

   Therefore all Dr. Bronner's coconut oil domestic production labeled after early June 2014, has been labeled with labels excluding this claim. Please see Attachment A for copies of the signed, dated label proofs from our label printing vendor demonstrating the removal of the claim on May 23, 2014.

Based on our sales projections and inventory turnover rates, we estimate that we currently have 4-8 weeks of finished goods coconut oil inventory in our warehouse that was labeled with the old labels containing the claim at issue, before the actions described above to modify the label and print new labels. We believe that by October, 2014, at the latest, all coconut oil sold will bear labels excluding this claim.

We have also taken the following additional, related actions to ensure compliance:

- Destroyed all remaining inventory of labels with the claim;
- Revised our website to remove this claim;
- Destroyed all ancillary marketing materials (~35,000 pieces) with the claim;
- Removed the claim from all of our international coconut oil labels and international marketing materials as well.

2. **Violation Noted: Food Labeling; *trans* fat (Section 403(q) of the Act [21 CFR 101.9(c)(2)(ii)])**

Dr. Bronner's Action Taken: Zero *trans* fat content declared on all future printed labels.

Thank you for bringing this *trans* fat requirement to our attention; we were previously unaware of the requirement. But upon receiving notice of the requirement in the Warning Letter, we immediately revised our coconut oil labels again to include the declaration of *trans* fat.

So effective as of July 16, 2014 all labels printed for domestic coconut oil (and international as well) will now include the *trans* fat declaration. Please see Attachment B for copies of the label proofs from our label printing vendor demonstrating the addition of the *trans* fat declaration on July 16, 2014. All products to which labels are affixed on or after August 1 will bear the new label including the trans fact information required by, and in the form required by, 21 CFR 101.9(c(ii)

We believe that these immediate actions taken correct the violations noted in the Warning Letter and will prevent any recurrence of the violations.

Thank you for your time and consideration.

Sincerely,

David Bronner
President
Dr. Bronner's Magic Soaps