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

Ebola-C Inc 11/18/14

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
FOOD AND DRUG
ADMINISTRATION
SILVER SPRING, MD 20993

TO: Todd Spinelli
Spinellico@yahoo.com
Cs_ebola@yahoo.com
www.ebola-c.com

FROM: The Food and Drug Administration and the Federal Trade Commission

RE: **Unapproved Products Related to Ebola and Notice of Potential Illegal Marketing of Products to Prevent, Treat or Cure Ebola Virus**

WARNING LETTER

This is to advise you that in October 2014 the U.S. Food and Drug Administration (FDA) and the United States Federal Trade Commission (FTC) reviewed your website at http://www.ebola-c.com from which you take orders for your product, “Ebola-C®.” We also note that the website at

http://www.ebolac.com automatically re-directs consumers to http://www.ebola-c.com. Based on FDA's review, we have determined that your website promotes your product for conditions that cause the product 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 website 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.

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

On your home page:

- The name of your product "Ebola –C"
- "DEFEND YOURSELF NOW!!!!! EBOLA-C®"
- "Because there is no cure for Ebola it is up to all Americans to defend themselves now! The only defense is to build our immune system to protect them from viruses that attack them."

On your Ebola-C product page (60 count and 120 count):

- "SPECIFICALLY FORMULATED FOR Ebola-C®"
- "[S]upports healthy wound healing…"

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 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 product identified above is offered for a condition that is 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 purposes. 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)].

The marketing and sale of unapproved or uncleared Ebola Virus-related products is a potentially significant threat to the public health. Therefore, FDA is taking urgent measures to protect consumers from products that, without approval or clearance by FDA, claim to diagnose, mitigate, prevent, treat or cure Ebola Virus in people.

You should take immediate action to ensure that your firm is not distributing, and does not distribute in the future, products intended to diagnose, mitigate, prevent, treat or cure the Ebola Virus that have not been approved or cleared by the FDA. The above is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that the products you market are in compliance with the Act and FDA's implementing regulations. We advise you to review the products you distribute, including the claims made for those products in websites, product labels, and other labeling and promotional materials, to ensure that products you distribute are not intended for uses that render them misbranded in violation of the Act. 21 U.S.C. §§ 331, 352. Within 15 working days, please send an email to **EbolaTaskForce-CFSAN@fda.hhs.gov (mailto:EbolaTaskForce-CFSAN@fda.hhs.gov)**, describing the actions that you have taken or plan to take to address your firm's violations. If your firm fails to take corrective action immediately, FDA may take enforcement action, such as seizure or injunction for violations of the Act, without further notice. Firms that fail to take corrective action may also be referred to FDA's Office of Criminal Investigations for possible criminal prosecution for violations of the Act and other federal laws.

If you are not located in the United States, please note that unapproved and uncleared products intended to diagnose, mitigate, prevent, treat, or cure the Ebola Virus offered for importation into the United States are subject to detention and refusal of admission. We will advise the appropriate regulatory or law enforcement officials in the country from which you operate that FDA considers your products listed above to be an unapproved or uncleared products that cannot be legally sold to consumers in the United States.

Please direct any inquiries concerning this letter to FDA at **EbolaTaskForce-CFSAN@fda.hhs.gov (mailto:EbolaTaskForce-CFSAN@fda.hhs.gov)** or by contacting Aaron Dotson at (240) 402-1922.

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. See *FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d

285, 300, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC v. Nat'l Urological Group*, *Inc*., 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009); *FTC v. Natural Solution*, *Inc.*, No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75,866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. See *In re Daniel Chapter One*, No. 9239, slip op. 18-20, 2009 WL 516000 (F.T.C.), 17-19 (Dec. 24, 2009) (http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf), *pet. for review den.*, 2010 WL 5108600 (D.C. Cir. Dec. 10, 2010).

The FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or Administrative Cease and Desist Order. An order also may require that you pay back money to consumers. Please notify FTC via electronic mail at **healthproducts@ftc.gov (mailto:healthproducts@ftc.gov)** within fifteen (15) working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Richard Cleland at 202-326-3088.

Sincerely,
/S/
Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

/S/
William A. Correll
Director
Office of Compliance
Center for Food Safety
And Applied Nutrition
Food and Drug Administration