Inspections, Compliance, Enforcement, and Criminal Investigations

Hyde Park Holistic Center 11/30/09

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
WASHINGTON, D.C. 20740

TO: info@drdahlman.com
www.drdahlman.com

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

RE: **Unapproved/Uncleared/Unauthorized Products Related to the H1N1 Flu Virus; and**

Notice of Potential Illegal Marketing of Products to Prevent, Treat or Cure the H1N1 Virus

DATE: November 30, 2009

WARNING LETTER

This is to advise you that the United States Food and Drug Administration ("FDA") and the United States Federal Trade Commission ("FTC") reviewed your website at the Internet address www.drdahlman.com on November 12, 2009. The FDA has determined that your website offers a product for sale that is intended to diagnose, mitigate, prevent, treat or cure the H1N1 Flu Virus in people. This product has not been approved, cleared, or otherwise authorized by FDA for use in the diagnosis, mitigation. prevention, treatment, or cure of the H1N1 Flu Virus. This product is your Immune Support Formula. The marketing of this product violates the Federal Food, Drug, and Cosmetic Act (FFDC Act). 21 U.S.C. §§ 331, 351, 352. We request that you immediately cease marketing unapproved, uncleared, or unauthorized products for the diagnosis, mitigation, prevention, treatment, or cure of the H1N1 Flu Virus.

In addition, FTC staff reminds you that 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 infection with the H1N1 virus, unless you possess well-controlled human clinical studies substantiating that the claims are true at the time they are made. More generally, it is against the law to make or exaggerate health 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. **Violations of the FTC Act may result in legal action in the form of a Federal District Court injunction or Administrative Order. An order also may require that you pay back money to consumers.**

Some examples of the claims on your website include:

On a webpage entitled, "The H1N1 Influenza":

"The main question about what a person can do to prevent bad swine flu symptoms revolves around what supplements might be beneficial to improve your immune system. Here are a few recommendations: These dosages are in case you get the flu this year and fear it's swine flu ... Trans Factor Plus Tri Factor ... Take 2 each day."

"Transfer Factor Plus Tri Factor ... The single most important supplement to take right now and while you have the flu to build your white cell count."

On a product webpage entitled "4 Life Transfer Factor Plus," under the subtitle "4 Life Transfer Factor Plus":

"There is no information I am about to give you that claims that 4 Life Transfer Factor Plus Tri Factor kills the H1N1 virus. But, hold on a second. If 4 Life Transfer Factor Plus Tri Factor enhances the abilities of the immune system ... and there are many scientific studies that support that fact ... then wouldn't a better functioning immune system be more potent to kill the H1N1 virus? Not the 4 Life Transfer Factor Plus Tri Factor killing the virus, but your own immune system doing the job? It is the purpose of the immune system to eliminate viruses from the body."

On the same webpage, under the subtitle "4Life Research Transfer Factor":

"Since the swine flu or H1N1 virus will most likely enter a person through the airways, wouldn't a stronger immune presence in the lungs be a good thing?"

"I firmly believe that use of this product will sufficiently upregulate your immune system and should be a primary part of your strategy to avoid the dangers of swine flu (H1N1 virus). Even if you do not contract swine flu and are just interested in maximizing your immune system function, this product is wonderful for optimizing your health!"

The Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, has determined that a public health emergency exists nationwide involving the H1N1 Flu Virus that affects or has the significant potential to affect national security. Following this determination and in response to requests from the U.S. Centers for Disease Control and Prevention, FDA issued letters authorizing the emergency use of certain unapproved and uncleared products or unapproved or uncleared uses of approved or cleared products, provided certain criteria are met, under 21 U.S.C. § 360bbb-3. The marketing and sale of unapproved or uncleared H1N1 Flu Virus-related products that are not authorized by and used in accordance with the conditions of an Emergency Use Authorization, is a potentially significant threat to the public health. Therefore, FDA is taking urgent measures to protect consumers from products that, without approval or authorization by FDA, claim to diagnose, mitigate, prevent, treat or cure H1N1 Flu Virus in people.

You should take immediate action to ensure that your firm is not marketing, and does not market in the future, products intended to diagnose, mitigate, prevent, treat or cure the H1N1 Flu Virus that have not been approved, cleared, or authorized 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 FFDC Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that the claims you make for your products do not adulterate or misbrand the products in violation of the FFDC Act. 21 U.S.C. §§ 331, 351, 352. **Within 48 hours, please send an email to FDAFLUTASKFORCECFSAN@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 FFDC 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 FFDC Act and other federal laws.

FDA is advising consumers not to purchase or use H1N1 Flu Virus-related products offered for sale that have not been approved, cleared, or authorized by FDA. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning marketing unapproved, uncleared and unauthorized H1N1 Flu Virus-related products in violation of the FFDC Act. This list can be found at www.accessdata.fda.gov/scripts/h1n1flu. Once the violative claims and/or products have been removed from your website, and these corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you are not located in the United States, please note that unapproved, uncleared, or unauthorized products intended to diagnose, mitigate, prevent, treat, or cure the H1N1 Flu 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 product listed above to be an unapproved, uncleared, or unauthorized product that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at FDAFLUTASKFORCECFSAN@fda.hhs.gov or by contacting Kathleen Lewis at 301-436-2148.

It is also your responsibility to ensure that the products you market are in compliance with the FTC Act. FTC staff strongly urge you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. The FTC also asks that you notify it via electronic mail at flu@ftc.gov within 48 hours of the specific actions you have taken to address the agency's concerns. If you have any questions regarding compliance with the FTC Act, please contact Karen Jagielski at 202-326-2509.

Very truly yours,
/S/

Mary K. Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission

/S/
Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
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Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA