Herbal Remedies 7/22/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

TO: information@herbalremedies.com

FROM: Food and Drug Administration

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

DATE: July 22, 2009

This is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address http://www.herbalremedies.comon July 13, 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 Sambucus Immune System Formula with Elderberry and Echinacea. 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.

The following is an example of a claim on your website:

- "Sambucol Immune System Elderberry Formula supports your natural defenses against the Flu, and Colds, and is especially popular during the winter season."

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 a 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(s} listed above to be unapproved, uncleared, or unauthorized products that cannot be legally sold to consumers in the United States.

Please direct any inquiries concerning this letter to FDA at **FDAFLUTASKFORCECFSAN@fda.hhs.gov.**

Sincerely,
/s/

Roberta F. Wagner
Director
Office of Compliance
Center for Food Safety
And Applied Nutrition