



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: [www.elixirs.com](http://www.elixirs.com) / [health@elixirs.com](mailto:health@elixirs.com)

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

Date: June 8, 2010

Subject: Urgent Message from the Food and Drug Administration and Federal Trade Commission  
Regarding H1N1 Flu Virus-Related Products Marketed by Your Firm

#### **WARNING LETTER**

This is to advise you that the United States Food and Drug Administration (FDA) and the United States Federal Trade Commission ("FTC") have reviewed your website at the Internet address [www.elixirs.com](http://www.elixirs.com) on December 22, 2009. The FDA has determined that your website offers products for sale that are intended to diagnose, mitigate, prevent, treat (including to treat the symptoms of) or cure the H1N1 Flu Virus in people. These products have not been approved or otherwise authorized by FDA for use in the diagnosis, mitigation, prevention, treatment (including treatment of symptoms), or cure of the H1N1 Flu Virus.

These products include, but are not limited to, Micro Nutrition Plus Flu Combo 2009-10, Micro Nutrition Plus Flu Influenzinum 200C, Micro Nutrition Plus Flu Kit Economy 1 oz Thymuline and 1 oz Winter Tonic, Micro Nutrition Plus Flu Protection Kit 3 Remedies, Micro Nutrition Plus Influenzinum 30C, BHI Bronchitis, BHI Bronchitis Chewable Tablets, BHI Flu Plus with Influenzinum, NaturalCare Flu Wellness Kit Flu and Respiratory Support, Heel Gallium Heel, Standard Homeopathic Nux Vomica 30C, Hyland's Nux Vomica 30X, Standard Homeopathic Nux Vomica 200C, Boiron Oscillococcinum, Micro Nutrition Plus Pnemococcinum 200C, Micro Nutrition Plus Pneumococcinum 30C, Micro Nutrition Plus Thymuline 12C Immune Support, Micro Nutrition Plus Upper Respiratory Balance, and Micro Nutrition Plus Winter Tonic Influenzinum Blend. The marketing of these products violates the Federal Food, Drug, and Cosmetic Act (FFDC Act). 21 U.S.C. §§ 331, 352. We request that you immediately cease marketing unapproved or unauthorized products for the diagnosis, mitigation, prevention, treatment (including treatment of symptoms), or cure of the H1N1 Flu Virus.

Some examples of the claims on your website include:

#### **Micro Nutrition Plus Flu Combo 2009-10 Seasonal Influenzinum and Thymuline**

- "Supportive help for current H1N1/swine flu concerns."
- "Seasonal Flu Vaccine 2009-10 is the homeotherapeutic vibration of the current H1N1 flu strains."
- "Treatment dose for relief of flu symptoms is 1 dose repeated 3 times a day."
- "Suggested dosing for treatment of flu symptoms as well as protection and exposure dosing."
- "Treatment dose for relief of flu symptoms is 1 dose repeated 3 times a day."

#### **Micro Nutrition Plus Flu Influenzinum 200C**

- "Influenzinum is available for emergency preparedness for flu mutations or for use when new strains are not available, such as the . . . current swine flu concern."
- "Influenzinum is a great flu defense to prevent spreading the flu and for relief of flu symptoms during fall, winter and spring illnesses."

#### **Micro Nutrition Plus Flu Kit economy 1 oz Thymuline and 1 oz Winter Tonic**

- "Winter Tonic is an influenza blend for H1N1/swine flu concerns."
- "Flu Kit with Thymuline and Winter Tonic can be taken before the flu strikes, or taken at first signs of illness. Use Flu Kit during illness to shorten duration and lessen symptoms."
- Winter Tonic is useful for unknown flu strains or mutations such as . . . swine flu, and before specific flu strains or vaccines are available.

#### **Micro Nutrition Plus Flu Protection Kit 3 Remedies**

- "Flu Protection Kit wit 3 important flu remedies: Upper Respiratory Balance, Thymuline and Influenzinum blend/Winter Tonic for H1N1 swine flu concerns."\  
"
- "Upper Respiratory Balance is useful for prevention and treatment of respiratory symptoms. H1N1/swine flu is respiratory affecting the throat and lungs. Upper Respiratory Balance contains remedies for the throat and remedies that support lung function."\  
"
- "Winter Tonic is our influenazinum blend which includes several respiratory/bird/swine influenzas, and is useful for unknown flu strains or mutations such as . . . swine flu, and before specific flu strains or vaccines are available."

#### **Micro Nutrition Plus Influenzinum 30C**

- "Influenzinum 30C can be used to lessen symptoms of current flu strains such as H1N1/swine flu."

#### **BHI Bronchitis**

- "Bronchitis offers natural help for respiratory flu, such as the current swine flu concern."

#### **BHI Bronchitis Chewable Tablets**

- Bronchitis offers natural help for respiratory flu, such as the current swine flu concern."

### **BHI Flu Plus with Influenzinum**

- "Flu Plus contains a non year specific Influenzinum to serve as simile protection from flu infections including flu mutations such as . . . current swine flu concern."
- "Flu Plus contains Anas Barbariae, Hepatis et coris extractum 200CK, is from a bird source and may have important implications with the current swine flu concern."

### **Flu Wellness Kit Flu and Respiratory Support**

- "Flu Wellness Kit has four products that protect the respiratory system for the current swine flu concern."\  
"
- "Oscillo to treat the flu right away."\  
"
- "Quebracho for respiratory flu . . ."

### **Heel Gallium Heel**

- "Gallium Heel can be used as a homeopathic anti-viral for respiratory flu, such as the current swine flu concern."

### **Standard Homeopathic Nux Vomica 30C**

- "Look at Nux Vomica as an 2009-2010 flu remedy. Homeopaths are looking at Nux Vomica as the simillimum for the current H1N1 / swine flu virus."

### **Hyland's Nux Vomica 30X**

- "Look at Nux Vomica as an 2009-2010 flu remedy. Homeopaths are looking at Nux Vomica as the simillimum for the current H1N1 / swine flu virus."

### **Standard Homeopathic Nux Vomica 200C**

- "Look at Nux Vomica as an 2009-2010 flu remedy. Homeopaths are looking at Nux Vomica as the simillimum for the current H1N1 / swine flu virus."

### **Boiron Oscilloccinum**

- "Anas barbariae hepatis et cordi extractum, a nosode made from a fowl bird source, so look at this product for emergency preparedness for swine flu, which is a mutation of bird or avian influenza, swine influenza and human influenza."
- "Use Oscilloccinum for fast relief of flu infection symptoms."

### **Micro Nutrition Plus Pneumococinum 200C**

- "Pneumococinum offers natural protection or help with symptoms for respiratory flu, such as the current swine flu concern."

### **Micro Nutrition Plus Pneumococinum 30C**

- "Pneumococinum offers natural protection and help from symptoms of respiratory flu, such as the current swine flu concern."

### **Micro Nutrition Plus Thymuline 12C Immune Support**

- "Thymuline may be used for allergies and respiratory concerns such as the current H1N1/swine flu concern."

### **Micro Nutrition Plus Upper Respiratory Balance\**

- "Upper Respiratory Balance supports the respiratory system. H1N1/swine flu is respiratory flu affecting the throat and lungs. Upper Respiratory Balance contains specific remedies for the throat and remedies that support lung function."

### **Micro Nutrition Plus Winter Tonic Influenzinum Blend**

- "Winter Tonic, an Influenzinum Blend, includes past years of influenza strains, including past swine . . . flu and the most current flu strains."
- Influenzinum Blend/Winter Tonic is an improved product to be used for the current Novel influenza A H1N1 swine flu."

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 (including to treat the symptoms of) or cure H1N1 Flu Virus in people.

We recognize that the labeling for your product(s) listed above identifies them as homeopathic drug products with active ingredient(s) measured in homeopathic strength(s)—Micro Nutrition Plus Flu Combo 2009-10 30C, Micro Nutrition Plus Flu Influenzinum 200C, Micro Nutrition Plus Flu Kit Economy 1 oz Thymuline and 1 oz Winter Tonic 12C and 6C, Micro Nutrition Plus Flu Protection Kit 3 Remedies 12C and 6C, Micro Nutrition Plus Influenzinum 30C, BHI Bronchitis 4X, 5X, 6X, and 30X, BHI Bronchitis Chewable Tablets 4X, 5X, 6X, and 30X, BHI Flu Plus with Influenzinum 3X-200CK, NaturalCare Flu Wellness Kit Flu and Respiratory Support (Oscillocochinum 200CK), Heel Gallium Heel 2X-4X, Standard Homeopathic Nux Vomica 30C, Hyland's Nux Vomica 30X, Standard Homeopathic Nux Vomica 200C, Boiron Oscillocochinum 200CK, Micro Nutrition Plus Pneumococchinum 200C, Micro Nutrition Plus Pneumococchinum 30C, Micro Nutrition Plus Thymuline 12C Immune Support, Micro Nutrition Plus Upper Respiratory Balance 6C, and Micro Nutrition Plus Winter Tonic Influenzinum Blend 6C. Nothing in the FFDC Act or the regulations issued under it exempts homeopathic drugs, including homeopathic biological products, from the regulatory requirements of the FFDC Act or its implementing regulations. We acknowledge that many homeopathic drug products are manufactured and distributed without FDA approval or authorization under enforcement policies set out in the FDA's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)." The enforcement discretion set forth in the CPG is not unlimited, however. The CPG states that it "delineates those conditions under which homeopathic drugs may ordinarily be marketed in the U.S." The qualifying word "ordinarily" indicates that the CPG specifically

contemplates that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action.

As stated above, the Secretary of Health and Human Services 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. A homeopathic drug product, including a homeopathic biological product, marketed without approval or authorization is not subject to the enforcement discretion set forth in the CPG when there is a nationwide public health emergency involving the disease that the product is intended to be used to diagnose, mitigate, prevent, treat (including to treat the symptoms of), or cure. Under these circumstances, the enforcement discretion set forth in the CPG does not apply to an unapproved or unauthorized product, regardless of its homeopathic status.

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 (including to treat the symptoms of) 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, or 352. Within 48 hours, please send an email to FDAFLUTASKFORCE-CDER@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](http://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 (including to treat the symptoms of), 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 or unauthorized products that cannot be legally sold to consumers in the United States.

Please direct any inquiries concerning this letter to FDA at FDAFLUTASKFORCECDER@fda.hhs.gov or by contacting Andrea Vincent at 301-796-3751.

It is also your responsibility to ensure that the products you market are in compliance with the FTC Act. Under the FTC Act, claims that your homeopathic products prevent, treat, or cure the H1N1 Flu Virus in people must be supported by competent and reliable scientific evidence consisting of well-controlled human clinical studies. FTC staff strongly urges you to review all claims relating to the treatment, prevention, or cure of H1N1 and remove those claims not supported by competent and reliable scientific evidence. The FTC also asks that you notify it via electronic mail at [flu@ftc.gov](mailto: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 Greg Fortsch at 202-326-3617.

Sincerely,

Deborah M. Autor, Esq Mary K. Engle

Director Associate Director  
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Food and Drug Administration

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