

# U.S. Food and Drug Administration

Protecting and Promoting Your Health

Home For Consumers Consumer Updates

#### For Consumers

#### **Beware of Fraudulent Flu Products**

**UPDATE:** Feb. 15, 2013. In the past week, FDA has sent an additional nine warning letters<sup>1</sup> to firms marketing fraudulent flu products, including an online firm marketing an "alternative to the flu shot," a firm selling an oral spray online and in major retail stores, and three firms marketing dietary supplements online. (The latter three firms' letters are co-signed by the Federal Trade Commission, which regulates the advertising of many consumer products.)

The remaining four warning letters were issued to online firms selling what they claim to be generic and other unapproved versions of oseltamivir phosphate (the active ingredient in Tamiflu). Tamiflu is an FDAapproved brand-name drug; no generic is approved in the U.S.



#### Flu Fraud Red Flags!

These flu claims on an unapproved product indicate that it may be fraudulent:

- reduces severity and length of flu
- · boosts your immunity naturally without a flu shot
- safe and effective alternative to flu vaccine
- prevents catching the flu
- effective treatment for flu
- faster recovery from flu
- supports your body's natural immune defenses to fight off flu
- Consumer Updates by E-mail<sup>2</sup>
- Consumer Updates RSS Feed<sup>3</sup>
  - Print & Share (PDF 206 KB)<sup>4</sup>
  - En Español<sup>5</sup>

## On this page:

- Types of Fraudulent Flu Products
- Fraudulent Online Pharmacies

As the flu continues to make people sick—and even cause deaths—scammers are alive and well, promotine

their fraudulent products to the unsuspecting public.

These scammers sell their products with claims to prevent, treat or cure the flu, even though they have not been tested and the Food and Drug Administration (FDA) has not approved them.

FDA warns consumers to steer clear of fraudulent flu products, which can be found online and in retail stores and may include products marketed as dietary supplements or conventional foods, drugs, nasal sprays and devices.

"As any health threat emerges, fraudulent products appear almost overnight," says Gary Coody, R.Ph., FDA's national health fraud coordinator. "Right now, so-called 'alternatives' to the flu vaccine are big with scammers."

"These unproven products give consumers a false sense of security," says Mary Malarkey, director of FDA' Office of Compliance and Biologics Quality. "There is no need to buy a product that claims to be an alternative to the vaccine. Flu vaccine is still available and it's not too late to get vaccinated."

The best way to prevent the flu is by getting vaccinated every year, and the Centers for Disease Control and Prevention (CDC) recommends the vaccine for adults and children over six months of age. To find a list of clinics, supermarkets, pharmacies and other vaccine providers in your neighborhood, visit www.flu.gov<sup>6</sup>, click on "Flu Vaccine Finder" and enter your zip code.

If you get the flu, two FDA-approved antiviral drugs—Tamiflu (oseltamivir) and Relenza (zanamivir)—are treatment options recommended by CDC. These prescription drugs can help fight the virus in your body and shorten the time you're sick. They can also be used to help prevent the flu.

## **Types of Fraudulent Flu Products**

There are no legally marketed over-the-counter (OTC) drugs to prevent or cure the flu. However, there ar legal OTC products to reduce fever and to relieve muscle aches, congestion, and other symptoms typically associated with the flu.

But unapproved drugs (which sometimes are marketed as dietary supplements), conventional foods (such as herbal teas) or devices (such as air filters and light therapies) are fraudulent if they make flu prevention, treatment or cure claims, says Coody, "because they haven't been evaluated by FDA for these uses."

On Jan. 25, 2013, FDA and the Federal Trade Commission jointly sent a warning letter to the company that markets "GermBullet," a nasal inhaler that makes flu prevention and treatment claims. The firm is required to remove the language in its labeling and advertising that violates federal law.

"If the company continues to sell the product without removing the deceptive and illegal language, the firn may be subject to enforcement action, which could include seizure of the products or other legal sanctions," says FDA Regulatory Counsel Brad Pace, J.D., of FDA's Health Fraud and Consumer Outreach Branch.

#### back to top

## **Fraudulent Online Pharmacies**

Online pharmacies present an opportunity for Internet scammers to take advantage of unsuspecting consumers. Legitimate online pharmacies do exist, but so do many websites that look like professional and legitimate pharmacies but are actually fraudulent and illegal.

These websites may be selling unapproved antiviral drugs. "Beware of websites that sell generic Tamiflu o Relenza," says FDA pharmacist Connie Jung, R.Ph., Ph.D., of FDA's Office of Drug Security, Integrity and Recalls. "Currently there are no FDA-approved generics available for these drugs on the U.S. market."

"With unapproved products, you really don't know what you're getting and can't be sure of the quality," adds Jung. "The products could be counterfeit, contaminated, or have the wrong active ingredient or no active ingredient. You could experience a bad reaction, or not receive the drug you need to get better."

Jung also warns consumers not to be tempted by an online seller that offers much lower prices than typically charged for prescription drugs by your local pharmacy. "Deep discounts on price are a good indicator of a fraudulent, illegal online pharmacy. You should avoid these online sellers because you might get products that are harmful to your health."

FDA encourages consumers to buy prescription drugs only through an online pharmacy that requires a vali prescription from a doctor or other authorized health care provider and is licensed by the state board of pharmacy (or equivalent state agency) where the patient is located.

Health fraud is pervasive and it's not always easy to spot a fraudulent product, says Coody. "If you're tempted to buy an unproven or little known treatment, especially if it's sold on the Internet, check with

your health care provider first."

This article appears on FDA's Consumer Updates page<sup>7</sup>, which features the latest on all FDA-regulated products.

Updated Feb. 15, 2013

back to top

### For More Information

- Health Fraud Scams<sup>8</sup>
- FDA Voice Video Blog--Don't Get Scammed: Beware of Health Fraud<sup>9</sup>
- FDA Voice Blog: FDA Cracks Down on Flu Product Scammers<sup>10</sup>
- FDA Warning Letters on Health Fraud<sup>11</sup>
- BeSafeRx -- Know Your Online Pharmacy<sup>12</sup>
- Buying Prescription Medicine Online: A Consumer Safety Guide<sup>13</sup>
- FDA Voice Blog: Flu Vaccines Still Available; Supplies Being Monitored<sup>14</sup>
- Flu.gov<sup>15</sup>
- CDC Says "Take 3" Actions To Fight The Flu<sup>16</sup>

## **Related Consumer Updates**

- 6 Tip-offs to Rip-offs: Don't Fall for Health Fraud Scams<sup>17</sup>
- Buying Medicines Online? Be Wary, FDA Says<sup>18</sup>
- The Possible Dangers of Buying Medicines Over the Internet<sup>19</sup>
- It's Not Too Late to Get a Flu Shot<sup>20</sup>
- Don't Be Fooled By Health Fraud Scams<sup>21</sup>
- Health Fraud Awareness (video)<sup>22</sup> [ARCHIVED]
- Innovations Expand Types of Seasonal Flu Vaccines<sup>23</sup>

Page Last Updated: 09/28/2013

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

Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website **Policies** 



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U.S. Department of Health & Human Services

# Links on this page:

- 1. /ForConsumers/ProtectYourself/HealthFraud/ucm255474.htm
- 2. http://service.govdelivery.com/service/subscribe.html?code=USFDA 9
- 3. /AboutFDA/ContactFDA/StayInformed/RSSFeeds/Consumers/rss.xml
- 4. /downloads/ForConsumers/ConsumerUpdates/UCM337700.pdf
- 5. /ForConsumers/ConsumerUpdates/ucm339047.htm
- 6. http://www.flu.gov
- 7. /ForConsumers/ConsumerUpdates/default.htm
- 8. /ForConsumers/ProtectYourself/HealthFraud/default.htm
- 9. http://blogs.fda.gov/fdavoice/index.php/2013/03/dont-get-scammed-beware-of-health-fraud/
- 10. http://blogs.fda.gov/fdavoice/index.php/2013/02/fda-cracks-down-on-flu-product-scammers-2/
- 11. /ForConsumers/ProtectYourself/HealthFraud/ucm255474.htm
- 12. http://www.fda.gov/besaferx
- 13. /Drugs/ResourcesForYou/ucm080588.htm
- 14. http://blogs.fda.gov/fdavoice/index.php/category/vaccines-blood-biologics/
- 15. http://flu.gov/
- 16. http://www.cdc.gov/flu/protect/preventing.htm
- 17. /ForConsumers/ConsumerUpdates/ucm341344.htm
- 18. /ForConsumers/ConsumerUpdates/ucm321121.htm
- 19. /ForConsumers/ConsumerUpdates/ucm048396.htm
- 20. /ForConsumers/ConsumerUpdates/ucm334805.htm
- 21. /ForConsumers/ConsumerUpdates/ucm278980.htm
- 22. /ForConsumers/ConsumerUpdates/ucm194727.htm
- 23. /ForConsumers/ConsumerUpdates/ucm369910.htm