## FDA NEWS RELEASE

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## FDA, FTC Warn Public of Fraudulent 2009 H1N1 Influenza Products

Offending web sites and illegal activity targeted for action

The U.S. Food and Drug Administration and the Federal Trade Commission are alerting the public to be wary of Internet sites and other promotions for products that claim to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 influenza virus. The agencies are also advising operators of offending web sites that they must take prompt action to correct and/or remove promotions of these fraudulent products or face enforcement action.

"Consumers who purchase products to treat the novel 2009 H1N1 virus that are not approved, cleared or authorized by the FDA for the treatment or prevention of influenza risk their health and the health of their families," said Michael Chappell, acting FDA Associate Commissioner for Regulatory Affairs. "In conjunction with the Federal Trade Commission, the FDA has developed an aggressive strategy to identify, investigate, and take regulatory or criminal action against individuals or businesses that wrongfully promote purported 2009 H1N1 influenza products in an attempt to take advantage of the current flu public health emergency."

Products that are offered for sale to the public with claims to diagnose, prevent, mitigate, treat, or cure infections caused by the H1N1 influenza virus that have not been proven to be safe and effective for these uses must be carefully evaluated. Many of these deceptive products are being sold over the Internet via illegitimate web sites. The operators of these web sites take advantage of the public's concerns about H1N1 influenza and their desire to protect themselves and their families. These fraudulent products come in all varieties and could include dietary supplements or other food products, or products purporting to be drugs, devices or vaccines. Such fraudulent products will not prevent the transmission of the virus or offer effective treatments against infections caused by the H1N1 influenza virus.

"The last thing any consumer needs right now is to be conned by someone selling fraudulent flu remedies," said FTC Chairman Jon Leibowitz. "The FTC will act swiftly against companies that resort to deceptive advertising."

Consumers are urged to contact their health care providers or legitimate medical supply services if they have questions or concerns about medical products or personal protective equipment. Consumers are also urged to visit the <u>FDA</u> and <u>Centers for Disease Control</u> and <u>Prevention</u> web sites for more information about this emergency, and to determine

which products the FDA has approved, cleared or authorized for use to diagnose, treat, prevent, mitigate or cure infections caused by H1N1 influenza virus.

Consumers should also visit FDA's web site for tips about how to protect themselves when buying medicines online: <u>http://www.fda.gov/buyonlineguide/</u>

The two antiviral drugs approved by the FDA for treatment and prophylaxis of the 2009 H1N1 influenza virus are Tamiflu (oseltamivir phosphate) and Relenza (zanamivir). Tamiflu and Relenza, in addition to their approved labeling, have Emergency Use Authorizations that describe specific authorized uses during this public health emergency.

For more information about FDA-approved antiviral drugs for influenza, see <u>http://www.fda.gov/cder/drug/antivirals/influenza/default.htm</u>.

For more information on CDC recommendations regarding use of antiviral drugs against the current novel 2009 H1N1 influenza strain, see http://www.cdc.gov/swineflu/?s\_cid=swineFlu\_outbreak\_001.

For more information about personal protective equipment see <u>http://www.fda.gov/cdrh/ppe/</u>.

At present, there are no licensed vaccines approved for this new H1N1 influenza virus.

Consumers are urged to report any suspected fraudulent products or criminal activity relating to FDA regulated products associated with H1N1 Flu Virus (Swine Flu), including the names of web sites that may be offering these products for sale, to the FDA by visiting:

http://www.fda.gov/oci/flucontact.html