FDA News

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FDA Authorizes Emergency Use of Influenza Medicines, Diagnostic Test in Response to Swine Flu Outbreak in Humans

The U.S. Food and Drug Administration, in response to requests from the U.S. Centers for Disease Control and Prevention, has issued Emergency Use Authorizations (EUAs) to make available to public health and medical personnel important diagnostic and therapeutic tools to identify and respond to the swine flu virus under certain circumstances. The agency issued these EUAs for the use of certain Relenza and Tamiflu antiviral products, and for the rRT-PCR Swine Flu Panel diagnostic test.

The EUA authority allows the FDA, based on the evaluation of available data, to authorize the use of unapproved or uncleared medical products or unapproved or uncleared uses of approved or cleared medical products following a determination and declaration of emergency, provided certain criteria are met. The authorization will end when the declaration of emergency is terminated or the authorization revoked by the agency.

Currently, Relenza is approved to treat acute uncomplicated illnesses due to influenza in adults and children 7 years and older who have been symptomatic for less than two days, and for the prevention of influenza in adults and children 5 years and older. Tamiflu is approved for the treatment and prevention of influenza in patients 1 year and older.

The EUAs allow for Tamiflu also to be used to treat and prevent influenza in children under 1 year, and to provide alternate dosing recommendations for children older than 1 year. In addition, under the EUAs, both medications may be distributed to large segments of the population without complying with the label requirements otherwise applicable to dispensed drugs, and accompanied by written information pertaining to the emergency use. They may also be distributed by a broader range of health care workers, including some public health officials and volunteers, in accordance with applicable state and local laws and/or public health emergency responses.

In authorizing an EUA for the rRT-PCR Swine Flu Panel diagnostic test, the FDA has determined that it may be effective in testing samples from individuals diagnosed with influenza A infections, whose virus subtypes cannot be identified by currently available tests. This EUA allows the CDC to distribute the swine flu test to public health and other qualified laboratories that have the needed equipment and the personnel who are trained to perform and interpret the results.

The test amplifies the viral genetic material from a nasal or nasopharyngeal swab. A positive result indicates that the patient is presumptively infected with swine flu virus but not the stage of infection. However, a negative result does not, by itself, exclude the possibility of swine flu virus infection.

The EUA authority is part of Project BioShield, which became law in July 2004.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.
--Online: www.fda.gov/MedWatch/report.htm
--Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
--Fax: (800) FDA-0178
--Phone: (800) FDA-1088

For more information:
FDA's Emergency Use Authorization of Medical Products Guidance, go to www.fda.gov/oc/guidance/emergencyuse.html.

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