

Swine Flu Issue Brief

Wednesday, 4-29-09 | 11:00 AM

FDA Emergency Use Authorizations (EUAs): What Are They and What Do They Mean for the Swine Flu Response?

By Brooke Courtney, JD, MPH

What Do the Swine Flu EUAs Mean for the Current Outbreak?

On April 27, 2009, the U.S. Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for the swine flu outbreak in response to requests by the Centers for Disease Control and Prevention (CDC). [1] One of the reasons the EUAs could be issued was because the U.S. Department of Health and Human Services (HHS) declared a public health emergency on April 26, 2009. [2] The EUAs will soon be published in *The Federal Register*.

The swine flu EUAs cover the following antivirals and diagnostic test to aid in the current response:

1. **Tamiflu**. Allow for the antiviral Tamiflu[®] (oseltamivir), which is manufactured by Roche, to be used to treat and prevent influenza in children under 1 year of age, and to provide alternate dosing recommendations for children older than 1 year (Tamiflu[®] is currently approved by the FDA for the treatment and prevention of influenza in patients 1 year and older, so the EUA expands the population that could receive the medicine).
2. **Tamiflu[®] and Relenza[®]** Allow for both Tamiflu[®] and Relenza[®] (zanamivir), which is manufactured by GlaxoSmithKline, to be distributed to large segments of the population without complying with federal label requirements otherwise applicable to dispensed drugs and to be accompanied by written information about the emergency use of the medicines.
3. **rRt-PCR Swine Flu Panel diagnostic test.** Allow CDC to distribute the rRT-PCR Swine Flu Panel diagnostic test to public health and other qualified laboratories that have the equipment and personnel to perform the testing and interpret the results. [1]

What Is an EUA?

In 2004, the Project BioShield Act (Public Law No. 108-276) gave the FDA Commissioner the authority to issue an EUA during a declared emergency “involving a heightened risk of attack on the public or U.S. military forces, or a significant potential to affect national security.” [3] The authority allows the FDA, after careful evaluation, 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. [1] In other words, an EUA can allow for medical countermeasures (e.g., medicines, vaccines) to be used during the

declared emergency “to diagnose, treat, or prevent serious or life-threatening diseases or conditions” caused by biological and other agents when “no adequate, approved, and available alternatives” exist. [3]

How Is an EUA Issued?

First, the HHS Secretary must declare an emergency based on certain criteria (e.g., a determination by the Secretary that a public health emergency exists or determinations of other specific types of emergencies by the Secretary of Homeland Security or Secretary of Defense). [3] The FDA Commissioner may then authorize an EUA after certain criteria are met (e.g., the Commissioner concludes that the agent specified in the emergency declaration can cause a serious or life-threatening disease, and that the known and potential benefits outweigh the known and potential risks of the product to diagnose, prevent, or treat the condition). Prior to authorizing an EUA, the FDA Commissioner consults with CDC and the National Institutes of Health (NIH), to the extent feasible during the emergency. [3]

The HHS Secretary is required to publish notice of each determination of actual or potential emergency and his or her declaration of emergency in *The Federal Register*. [3] Notice of the EUA (as well as a termination or revocation of the EUA) is also published in *The Federal Register*. [3]

What Types of Products Could an EUA Cover?

Potential products that could qualify for an EUA include drugs, biological products (e.g., vaccines, blood products), and medical devices (e.g., *in vitro* diagnostics). [3] These products include unapproved products (i.e., those that have not been approved or cleared by the FDA) and unapproved uses of approved products (i.e., unapproved uses of approved drugs and approved or cleared devices). [3]

For How Long Is an EUA Effective?

An EUA remains in effect until the emergency declaration is terminated or until the FDA revokes the authorization. Using an EUA product after the declaration (except when used by patients who began the treatment when the declaration was still in effect) would subject it to investigational product regulations. [3]

Have EUAs Been Issued Before the Swine Flu Outbreak?

Yes. For example, before the swine flu EUAs, an EUA was issued for emergency kits containing the antibiotic doxycycline that could be stored at the homes of eligible United States Postal Service (USPS) workers who participate in the federal Cities Readiness Initiative, a program for dispensing antibiotics to the public after an anthrax attack. [4]

Even though doxycycline hyclate tablets are approved by the FDA for post-exposure prophylaxis of inhalational anthrax, the EUA was needed in this case because the kits would include information (e.g., fact sheets, home preparation instructions for people who cannot swallow pills) that was not part of the approved new drug application (NDA) or abbreviated new drug application (ANDA) for doxycycline hyclate tablets (100 mg). [4] Dispensing medicine with written information that is not part of the FDA-approved labeling could render the drug misbranded and unapproved in certain ways, so an EUA was needed.

Where Can I Find Additional Information About EUAs?

FDA Guidance: Emergency Use Authorization of Medical Products (July 2007)

www.fda.gov/oc/guidance/emergencyuse.html

Swine Flu: Emergency Use Authorization (EUA) of Medical Products and Devices (CDC)

<http://www.cdc.gov/swineflu/eua/>

Note: This Issue Brief does not provide legal advice. Those potentially affected by the topics discussed should seek further guidance from their legal counsel.

References

1. FDA authorizes emergency use of influenza medicines, diagnostic test in response to swine flu outbreak in humans [news release]. Rockville, MD: U.S. Food and Drug Administration. April 27, 2009. <http://www.fda.gov/bbs/topics/NEWS/2009/NEW02002.html>. Accessed April 28, 2009.
2. HHS declares public health emergency for swine flu [news release]. Washington, DC: U.S. Department of Health and Human Services. April 26, 2009. <http://www.hhs.gov/news/press/2009pres/04/20090426a.html>. Accessed April 27, 2009. The press release for the public health emergency declaration noted that the declaration “will help HHS prepare for prevention and mitigation activities by enabling the Food and Drug Administration (FDA) emergency use authorizations of drugs, devices, or medical tests under certain circumstances.”
3. U.S. Food and Drug Administration. *FDA Guidance: Emergency Use Authorization of Medical Products*. July 2007. www.fda.gov/oc/guidance/emergencyuse.html.
4. 73 FR 62507 (October 21, 2008).

Press Contact

Molly D’Esopo

443-573-3307

molly_desopo@upmc-biosecurity.org