

ATTACHMENT 1:

Questions and Answers Regarding Termination of the Emergency Use Authorizations (EUAs) for Tamiflu (oseltamivir) and Relenza (zanamivir)

During the 2009 H1N1 influenza public health emergency, FDA issued Emergency Use Authorizations (EUAs) that authorized certain unapproved uses of Tamiflu and Relenza.

On June 21, 2010, the U.S. Food and Drug Administration (FDA) notified the Centers for Disease Control and Prevention (CDC) that these EUAs will terminate when the Public Health Emergency determination for 2009 H1N1 Influenza expires on June 23, 2010. Therefore, after June 23, 2010, the EUAs authorizing the unapproved uses of Tamiflu and Relenza will no longer be in effect.

Q1. What is an EUA?

A. An EUA may be issued by FDA to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents.

Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), amended by the Project BioShield Act of 2004, permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.

Q2. What unapproved uses for Tamiflu and Relenza were authorized under the 2009 H1N1 influenza public health emergency EUAs?

A. Under the EUA, Tamiflu was authorized:

- To treat and prevent influenza in children under 1 year of age. Due to limited experience in infants less than 3 months of age, use of Tamiflu for prevention of 2009 H1N1 flu in this age group was not routinely recommended, but Tamiflu could have been used if the need was considered critical, e.g., if exposure was significant, if risk of severe illness was considered high.
- With dosing recommendations for children under the age of 1 year

Under the EUAs, Tamiflu and Relenza were authorized:

- For use at later time points after onset of symptoms. For example, for use in patients who were symptomatic for more than 2 days or in patients sick enough to require hospitalization (i.e., patients with complicated influenza)
- To be distributed or dispensed by public health authorities without all of the FDA-required prescription label information
- To be accompanied by certain written emergency use information (Fact Sheets)

- To be distributed by public health officials or other volunteers to recipients in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction
- For certain lots of Tamiflu for Oral Suspension, Tamiflu Capsules, and Relenza Inhalation Powder, for use beyond their labeled expiration dates

Q3. After the termination of the EUAs, what are FDA's recommendations regarding the previously-authorized, unapproved uses of Tamiflu and Relenza?

A. After June 23, 2010, Tamiflu and Relenza should be distributed and dispensed in compliance with FDA regulations and State laws, and in accordance with FDA-approved product labeling.

Tamiflu is approved by the FDA for the following indications:

- Treatment of uncomplicated acute illness due to influenza A and B virus infection in patients 1 year and older who have been symptomatic for no more than two days.
- Prophylaxis (prevention) of influenza A and B virus in patients 1 year and older.

Relenza is approved by the FDA for the following indications:

- Treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than two days.
- Prophylaxis (prevention) of influenza A and B virus in adults and pediatric patients 5 years of age and older.

Q4. The EUA for Tamiflu provided dosing recommendations for Tamiflu in children less than 1 year of age. Has this dosing regimen been approved by FDA?

A. No. Tamiflu is approved for patients 1 year and older, and FDA has not approved dosing for children less than 1 year of age.