

Updated Questions and Answers: 2009 H1N1 Flu Virus and Emergency Use Authorization of Tamiflu and Relenza

Note: This set of Questions and Answers was initially issued by FDA in July 2009. Due to the evolving nature of the 2009 H1N1 public health emergency, FDA has amended the original Emergency Use Authorizations (EUAs) for both Tamiflu and Relenza. The Updated Questions and Answers reflect the information in the amended EUAs.

Q1. What is FDA announcing today and how does this announcement change the previous Emergency Use Authorizations for Tamiflu and Relenza?

A. In April 2009, FDA issued Emergency Use Authorizations (EUA) for Tamiflu and Relenza as part of the federal government's response to the 2009 H1N1 public health emergency. The EUAs authorized the use of Tamiflu and Relenza beyond their approved indications. See question 3 for authorized uses of Tamiflu and Relenza under the EUAs.

In July 2009, FDA amended the Tamiflu EUA to authorize the use of [certain lots](#) of expired or expiring Tamiflu for Oral Suspension that were still good for use beyond their expiration dates. The authorized lots were part of the Strategic National Stockpile (SNS) and had been tested through the federal government's Shelf-Life Extension Program (SLEP).

Today, FDA is announcing amendments to the Tamiflu and Relenza EUAs that make two changes. First, the amendments authorize the use of [certain lots](#) identified by FDA of expired or expiring Tamiflu Capsules and Relenza Inhalation Powder, including product held by public health authorities and private sector entities¹, for the duration of the declared public health emergency. FDA's decision that these lots are acceptable for use beyond their expiration dates is supported by FDA's approval of applications submitted by the manufacturers of Tamiflu and Relenza that extended the expiration dates of certain Tamiflu and Relenza products.

Second, for the first time the EUAs permit entities that are not public health authorities and are not acting as part of the emergency response of an "Authority Having Jurisdiction"* to utilize certain FDA-identified lots of expired or expiring Tamiflu Capsules and Relenza Inhalation Powder beyond their expiration dates in conformance with the conditions set out in the EUA. See response to Q5.

In addition, FDA made clarifications to the accompanying [Tamiflu Fact Sheet for Health Care Providers](#), the [Relenza Fact Sheet for Health Care Providers](#), the [Tamiflu Fact Sheet for Patients and Parents/Caregivers](#) and [Relenza Fact Sheet for Patients and Parents/Caregivers](#) to include this new information. The Tamiflu Fact Sheet for Health Care Providers was also updated to include dosing recommendations based on weight for children younger than 1 year of age.

¹In these Q&As, the term private sector entities is used to refer to entities that are not public health authorities. Examples include corporations, hospitals (public and private), wholesalers, pharmacies, and individuals.

Q2. What are the FDA approved indications for Tamiflu and Relenza?

A. 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.

Q3. What uses of Tamiflu and Relenza are authorized under the EUA?

A. Under the EUA, Tamiflu is authorized:

Updated Questions and Answers: 2009 H1N1 Flu Virus and Emergency Use Authorization of Tamiflu and Relenza

- To treat and prevent influenza in children under 1 year of age (due to limited experience, use of Tamiflu for prevention of 2009 H1N1 flu in infants less than 3 months of age is not routinely recommended but Tamiflu may be used if the need is considered critical, e.g., exposure is significant, risk of severe illness is considered high.)
- With dosing recommendations for children under the age of 1 year

Under the EUAs, Tamiflu and Relenza are authorized:

- For use at later time points (in patients who are symptomatic for more than 2 days, in patients sick enough to require hospitalization, i.e., patients who do not have “uncomplicated acute illness” per se)
- 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, to be used beyond their expiration dates

Q4. What Tamiflu and Relenza products are covered under the original and amended EUAs?

A. The original EUAs, including the July 2009 amendment to the Tamiflu EUA, covered Tamiflu and Relenza distributed under the authority of the Centers for Disease Control and Prevention (CDC) and appropriate public health authorities. The original EUAs also covered Tamiflu and Relenza from private sector entities who were distributing the product as part of the emergency response of an Authority Having Jurisdiction. Any private entity storing or distributing Tamiflu and Relenza outside of the emergency response of an Authority Having Jurisdiction was not within the scope of the original EUAs for Tamiflu and Relenza.

Today, FDA amended the EUA to authorize the use of certain [FDA identified lots](#) of Tamiflu and Relenza distributed by private sector entities beyond their expiration dates during the period of the declared emergency, even if the private sector entity is distributing outside of the emergency response of an Authority Having Jurisdiction. Additionally, private sector entities distributing Tamiflu and Relenza as part of the emergency response of an Authority Having Jurisdiction will continue to be covered under the amended EUAs.

The amended EUAs only authorize private sector entities to distribute Tamiflu and Relenza that are included in the [FDA identified lots](#) of expired or expiring Tamiflu and Relenza.

Therefore, the amended EUAs apply to certain lots of Tamiflu and Relenza distributed by CDC and appropriate public health authorities, and to certain [FDA identified lots](#) of expired and expiring Tamiflu and Relenza distributed by CDC, public health authorities, and private sector entities. CDC, public health authorities, and private sector entities storing and distributing Tamiflu and Relenza under the EUAs must follow the terms and conditions of the EUAs as stated in the EUAs Letter of Authorization ([Tamiflu EUA](#) and [Relenza EUA](#)).

Q5. Do the authorized uses of Tamiflu and Relenza (see Q3) apply to private sector entities under the amended EUAs?

A. The amended EUAs for Tamiflu and Relenza cover private sector entities in two situations: First, they apply if the drugs are distributed under the authority of the CDC or an Authority Having Jurisdiction. Second, the amended EUAs cover certain [FDA identified lots](#) of expired or expiring Tamiflu and Relenza that are distributed by private sector entities, subject to the terms and conditions of the EUAs.

Tamiflu and Relenza that are prescribed and dispensed by a private sector entity, as part of the emergency response of an Authority Having Jurisdiction, in compliance with the terms and conditions of the amended EUAs, are covered under the EUAs as amended.

Updated Questions and Answers: 2009 H1N1 Flu Virus and Emergency Use Authorization of Tamiflu and Relenza

Under the amended EUAs for Tamiflu and Relenza, certain [FDA identified lots](#) of Tamiflu and Relenza that are prescribed and dispensed by a private sector entity, meeting the terms and conditions of the amended EUAs, would also be covered, even if the private sector entity is acting outside of the scope of the emergency response of an Authority Having Jurisdiction.

However, the amended EUAs do not cover Tamiflu and Relenza prescribed or dispensed for an unapproved (“off-label”) use authorized under the EUA if 1.) the Tamiflu and Relenza being prescribed or dispensed by a private sector entity is not part of the emergency response of an Authority Having Jurisdiction and 2.) the Tamiflu or Relenza has not been identified by FDA as part of an [authorized lot](#) of expired or expiring Tamiflu and Relenza.

Q6. Under the amended EUAs for Tamiflu and Relenza, what information should be given to a patient?

A. The [Tamiflu Fact Sheet for Patients and Parents/Caregivers](#) and [Relenza Fact Sheet for Patients and Parents/Caregivers](#) authorized under the Tamiflu and Relenza amended EUAs must be made available to the patient or recipient of the product through appropriate means, which may include distribution of the Fact Sheet with Tamiflu and Relenza.

Q7. Under the amended EUAs for Tamiflu and Relenza, what does it mean to make medication information available “through appropriate means”?

A. A condition of the amended EUAs for Tamiflu and Relenza provides that public health authorities and private entities (to the extent they are distributing certain [FDA identified lots](#) of Tamiflu and Relenza) make available “through appropriate means” Fact Sheets developed for recipients and for healthcare providers for this emergency use. Making these Fact Sheets available “through appropriate means” can include (but is not limited to) handing the information to the recipient with the product, or otherwise making it available for reference at the location where medications are being distributed, depending on the circumstances of the emergency.

Q8. In the amended EUAs for Tamiflu and Relenza, what kind of “additional information,” which is consistent with the Fact Sheets, can be provided by the appropriate public health authorities?

A. Examples of “additional information” include direct translations of the Fact Sheets into other languages, a poster display, and DVD or television announcements that relay the information contained in the Fact Sheets.

Q9. Why does the amended EUA for Tamiflu state that it covers Strategic National Stockpile (SNS) assets and those authorized under SLEP, but the EUA for Relenza does not make the same statement?

A. Both the amended EUAs for Tamiflu and Relenza cover Tamiflu and Relenza distributed under the authority of the CDC, including SNS assets, appropriate public health authorities, and certain [FDA identified lots](#) of Tamiflu and Relenza under the direction of private sector entities. However, while Tamiflu is part of the federal government’s Shelf Life Extension Program (SLEP), Relenza is not. For this reason, reference to SLEP in the Relenza EUA was unnecessary.

* The term "Authority Having Jurisdiction" is used in the [Public Readiness and Emergency Preparedness Act declaration for antivirals](#) and means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g. law enforcement, public health) range or sphere of authority.