

Stockpiled Antivirals at or Nearing Expiration

(Source: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>)

During this public health emergency, the FDA has issued Emergency Use Authorizations that expand access to medical products that may become necessary.

Two antiviral treatments covered by Emergency Use Authorizations, Tamiflu (oseltamavir) and Relenza (zanamivir), may already be included in many emergency stockpiles.

All companies, U.S. states and localities, and other organizations with Tamiflu and Relenza that are approaching, or past, the labeled expiration date, are urged to consider keeping it while the U.S. Department of Health and Human Services evaluates options, including those that may allow for their use if needed during this 2009 H1N1 flu virus outbreak.

If the stockpiling entity decides to retain expired or soon-to-expire Tamiflu and Relenza, it should be maintained and monitored under the product's labeled storage conditions.

These organizations are also urged to contact the FDA's Emergency Operations Center with information on how much Tamiflu and Relenza in their stockpiles is at or approaching expiration.

This information should be reported to:

FDA's Emergency Operations Center
Phone number: 301-443-1240.

This statement is not directed to individual patients who already have these two products in their homes. Individuals with these products should continue to follow the directions from their doctor, pharmacist or other health care professional.

Storage of Tamiflu (oseltamivir phosphate)

Tamiflu should be stored at controlled room temperature. The United States Pharmacopeia (USP) defines controlled room temperature as a temperature that is maintained by thermostat and is between 20 and 25°C (68 to 77° F).

Under the Emergency Use Authorization (EUA) for Tamiflu, the storage requirements for Tamiflu held in public health authority stockpiles may be waived for a maximum of 90 days (consecutive or non-consecutive) from the date of shipment to the public health authority. This waiver is limited in that Tamiflu may be stored with temperature excursions in excess of 40°C (104°F) for a total cumulative period of 14 days (consecutive or non-consecutive) within the 90-day period. Other temperature excursions that are outside of the labeled temperature storage conditions are permitted within the 90-day period provided they do not exceed 40°C (104° F).

Authorization of Use for Certain Lots of Expired Tamiflu for Oral Suspension

Twenty-six lots (batches) of Tamiflu for Oral Suspension have been tested in the federal government’s Shelf Life Extension Program (SLEP)¹. FDA has determined that the data from scientific testing and analysis support the use of these lots beyond their expiration dates. FDA has authorized the use of these lots beyond their expiration dates under an Emergency Use Authorization.

The following table lists the lots of Tamiflu for Oral Suspension that have passed SLEP testing. The table also lists the original expiration dates of these lots and information about their use beyond their expiration dates until their “Date Supported by SLEP Testing.” Please note, however, that these lots will only be authorized for use beyond their expiration dates under the Emergency Use Authorization (EUA) during the period of time that the Secretary of the Department of Health and Human Services’ (HHS’s) April 26, 2009 declaration of emergency justifying the EUA remains in effect. The declaration will expire in one year, on April 26, 2010, unless it is terminated earlier, but could be extended by the Secretary of HHS if certain criteria are met.

Tamiflu for Oral Suspension

Lot number	Manufacturer’s original expiry date	Date Supported by SLEP Testing
Lots recently delivered via AZ’s Strategic National Stockpile		
B1045	May 31, 2005	February 28, 2010
B1047	November 30, 2005	February 28, 2010
B1048	January 31, 2006	August 31, 2010
Other lots that are included in the SLEP testing		
B1046	November 30, 2005	February 28, 2010
B1185	June 30, 2009	May 31, 2011
B1186	June 30, 2009	May 31, 2011
B1187	June 30, 2009	May 31, 2011
B1042	January 31, 2005	May 31, 2011
B1050	January 31, 2006	August 31, 2010
B1051	January 31, 2006	August 31, 2010
B1052	January 31, 2006	August 31, 2010
B1053	January 31, 2006	August 31, 2010
B1054	January 31, 2006	August 31, 2010
B1055	January 31, 2006	August 31, 2010
B1065	June 30, 2006	August 31, 2010
B1082	May 31, 2007	May 31, 2011
B1097	June 30, 2007	May 31, 2011
B1098	June 30, 2007	May 31, 2011

B1188	June 30, 2009	May 31, 2011
B1189	June 30, 2009	May 31, 2011
B120553	August 8, 2009	October 31, 2011
B120650	August 8, 2009	October 31, 2011
B1213	November 1, 2009	October 31, 2011
B1214	November 1, 2009	October 31, 2011
B1216	November 1, 2009	October 31, 2011

The U.S. Department of Health and Human Services continues to evaluate options for antiviral drugs that are approaching, or past, their expiration dates.

1. Certain antiviral medications that are at or nearing their expiration date may be tested under the federal government's Shelf-Life Extension Program (SLEP). Under SLEP, FDA conducts scientific testing and analysis to see if specific lots of TAMIFLU can be used beyond their expiration dates. If the product passes testing, FDA determines that the shelf life of the product can be extended beyond its expiration date.

Additional Information:

For more information from the Arizona Board of Pharmacists, please visit our website at <http://azpharmacy.gov/faqs.asp> or for questions on Arizona's Strategic National Stockpile, please contact Kaitlin Henslee at (602)350-0081 or Lisa Speissegger at (602)448-7628.

This document has been reviewed and authorized for use by:

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(for physician/patient information, see *Information for Healthcare Professionals - Authorization of Use of Expired Tamiflu for Oral Suspension*)