

ATTACHMENT 2

Update Regarding Stockpiled Antivirals at or Nearing Expiration

During the 2009 H1N1 influenza public health emergency, the FDA issued Emergency Use Authorizations (EUAs) authorizing the emergency use of certain expired lots of Tamiflu (oseltamivir phosphate) and Relenza (zanamivir) based on scientific review and analysis that found the drugs could be used beyond their labeled expiration dates.

On June 21, 2010, the U.S. Food and Drug Administration (FDA) notified the Centers for Disease Control and Prevention (CDC) that these EUAs for Tamiflu and Relenza will terminate when the Public Health Emergency determination for 2009 H1N1 Influenza expires on June 23, 2010. Therefore, after June 23, 2010, the emergency use of certain expired lots of Tamiflu and Relenza will no longer be authorized under the EUAs.

This statement provides CDC updated information regarding these identified lots for purposes of informing public health authorities. This statement is not directed to individual patients who already have Tamiflu and/or Relenza in their homes. If they have Tamiflu or Relenza in their homes with expired date, they should discard the product.

For additional information, contact **FDA's Division of Drug Information at 1-888-463-6332**

Storage of Tamiflu and Relenza

If Tamiflu and/or Relenza is retained, it must be maintained and monitored under the product's labeled storage conditions. Tamiflu and Relenza 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).

Disposition of Identified Lots of Tamiflu and Relenza

Tamiflu Capsules and Relenza Inhalation Powder

FDA approved supplemental New Drug Applications for Relenza Inhalation Powder and Tamiflu Capsules that provided an expiration dating period of seven years. Approvals of new drug applications are generally prospective. FDA is aware that the following lots of Relenza Inhalation Powder and Tamiflu Capsules are currently packaged with an expiration date less than seven years. Provided that the products have been stored under the labeled storage conditions, FDA believes it would be scientifically supportable for the expiry extension (for a maximum of seven years) to apply to these lots that have already been manufactured. Thus FDA does not intend to take an enforcement action with regard to the following lots of Relenza Inhalation Powder and Tamiflu Capsules that are retained

for potential use in future emergencies, provided that the products have been stored under the labeled storage conditions.

To minimize confusion on the part of healthcare professionals and patients, FDA recommends, prior to dispensing, that the identified lots be relabeled/repackaged by an FDA registered firm in accordance with applicable Current Good Manufacturing Practice (CGMP) requirements under 21 CFR 210, 211. (A relabeling/repackager firm’s registration status can be confirmed/verified at the following website: <http://www.fda.gov/cder/dfars/default.htm>).

For Tamiflu Capsule blister packages and Relenza Diskhalers:

The registered relabeler/repackager should place the product in a sleeve and include the following printed statement with the product:

“FDA has determined that it is scientifically supportable to use this product beyond the printed expiration date that is on original label and internal components until [Enter 7 Year Expiry Date from Tables below]”

Tamiflu Capsules 75mg Blister Package

Lot Number	Unit (10 capsules per blister package)	Manufacturer’s original expiry date	7 Year Expiry Date
B1060	Blister package	November 30, 2007	November 03, 2010
B1061-01	Blister package	November 30, 2007	November 04, 2010
B1061-02	Blister package	November 30, 2007	November 04, 2010
B1062	Blister package	December 31, 2007	December 08, 2010
B1063	Blister package	December 31, 2008	December 11, 2010
B1079	Blister package	October 31, 2009	October 31, 2011
B1080	Blister package	October 31, 2009	October 31, 2011
B1081	Blister package	October 31, 2009	October 31, 2011
B1082	Blister package	October 31, 2009	October 31, 2011
B1082-01	Blister package	October 31, 2009	October 31, 2011
B1082-02	Blister package	October 31, 2009	October 18, 2011
B1086	Blister package	November 30, 2009	November 30, 2011
B1093	Blister package	November 30, 2009	November 26, 2011
B1094	Blister package	November 30, 2009	November 29, 2011

Relenza Inhalation Powder Diskhaler

Lot Number	Manufacturer’s original expiry date	7 Year Expiry Date
153	November 30, 2009	November 30, 2011
154	November 30, 2009	November 30, 2011
154A	November 30, 2009	November 30, 2011
237	July 31, 2011	July 31, 2013

Lot Number	Manufacturer's original expiry date	7 Year Expiry Date
238	July 31, 2011	July 31, 2013
270	September 30, 2011	September 30, 2013
271	September 30, 2011	September 30, 2013
273	September 30, 2011	September 30, 2013
274	September 30, 2011	September 30, 2013
275	September 30, 2011	September 30, 2013
276	September 30, 2011	September 30, 2013
277	September 30, 2011	September 30, 2013
279	September 30, 2011	September 30, 2013
280	September 30, 2011	September 30, 2013
281	September 30, 2011	September 30, 2013
282	September 30, 2011	September 30, 2013
287	September 30, 2011	September 30, 2013
292	October 31, 2011	October 31, 2013
293	October 31, 2011	October 31, 2013
294	October 31, 2011	October 31, 2013
305	October 31, 2011	October 31, 2013
306	October 31, 2011	October 31, 2013
307	October 31, 2011	October 31, 2013
308	October 31, 2011	October 31, 2013
374	January 31, 2012	January 31, 2014
518	August 31, 2012	August 31, 2014
519	August 31, 2012	August 31, 2014
521	September 30, 2012	September 30, 2014
522	October 31, 2012	October 31, 2014
523	October 31, 2012	October 31, 2014
524	October 31, 2012	October 31, 2014
525	October 31, 2012	October 31, 2014
526	October 31, 2012	October 31, 2014
7ZP0106	November 30, 2012	November 30, 2014
7ZP0862	November 30, 2012	November 30, 2014
7ZP1431	November 30, 2012	November 30, 2014
7ZP3799	July 31, 2012	July 31, 2014
7ZP3990	August 31, 2012	August 31, 2014
7ZP4325	August 31, 2012	August 31, 2014
7ZP5504	August 31, 2012	August 31, 2014
7ZP7104	May 31, 2012	May 31, 2014
7ZP8530	October 31, 2012	October 31, 2014
7ZP8753	October 31, 2012	October 31, 2014
7ZP8870	October 31, 2012	October 31, 2014
8ZP3152	December 31, 2012	December 31, 2014

Tamiflu Capsules bottles:

The registered relabeler/repackager should place a sticker over the old expiry date that does not obstruct any of the other label information with the appropriate 7 Year Expiry Date from the table below and the following statement:

“FDA has determined that it is scientifically supportable to use this product until [Enter 7 Year Expiry Date from Tables below]”

Tamiflu Capsule 75 mg Bottles

Lot Number	Unit (10 capsules per bottle)	Manufacturer’s original expiry date	7 Year Expiry Date
B1090	Bottles	November 30, 2009	November 30, 2011
B1100	Bottles	December 31, 2009	December 31, 2011
B1100-01	Bottles	December 31, 2009	December 31, 2011
B1109	Bottles	January 31, 2010	January 31, 2012
B1118	Bottles	April 30, 2010	April 30, 2012
B1122	Bottles	May 31, 2010	May 31, 2012
B1148	Bottles	July 31, 2010	July 31, 2012
B1149	Bottles	July 31, 2010	July 31, 2012
U2011	Bottles	September 30, 2010	September 30, 2012
U2012	Bottles	September 30, 2010	September 30, 2012
U2013	Bottles	September 30, 2010	September 30, 2012
U2017	Bottles	January 31, 2011	January 31, 2013
U2021	Bottles	March 31, 2011	March 31, 2013
U2051	Bottles	August 31, 2011	August 31, 2013
U400050	Bottles	May 31, 2011	May 31, 2013
U400150	Bottles	May 31, 2011	May 31, 2013
U400250	Bottles	May 31, 2011	May 31, 2013
U4008-10	Bottles	August 31, 2011	August 31, 2013
U4030-02	Bottles	October 31, 2011	October 31, 2013
U4031-01	Bottles	October 31, 2011	October 31, 2013
U4032-01	Bottles	October 31, 2011	October 31, 2013
U4033-01	Bottles	October 31, 2011	October 31, 2013
U4034-01	Bottles	October 31, 2011	October 31, 2013
U4037-01	Bottles	October 31, 2011	October 31, 2013

The following lots of Tamiflu Capsules already have an expiration dating period of 7 years. Therefore these lots can be retained only until their manufacturer’s original expiry date on the label.

Tamiflu 30 mg Capsules

Lot Number	Unit (10 caps per bottle)	Manufacturer's original expiry date
B1003-50	Bottles	November 30, 2014
B1004-50	Bottles	November 30, 2014
B1005	Bottles	November 30, 2014

Tamiflu 45 mg Capsules

Lot Number	Unit (10 caps per bottle)	Manufacturer's original expiry date
B1003-50	Bottles	November 30, 2014
B1004	Bottles	November 30, 2014

Tamiflu 75 mg Capsules

Lot Number	Unit (10 caps per bottle)	Manufacturer's original expiry date
U4067	Bottles	August 31, 2014
U4069	Bottles	September 30, 2014
U4070	Bottles	September 30, 2014
U4075	Bottles	November 30, 2014
U4078	Bottles	November 30, 2014

Tamiflu for Oral Suspension

Unlike Tamiflu Capsules and Relenza Inhalation Powder, FDA has not approved an expiration dating period of seven years for Tamiflu for Oral Suspension. Therefore, the following lots of Tamiflu for Oral Suspension that were authorized for use under the EUA should be destroyed utilizing the facilities' pharmaceutical disposal procedures and in compliance with all applicable laws.

Lot Number	Manufacturer's original expiry date
B1042	January 31, 2005
B1045	May 31, 2005
B1046	November 30, 2005
B1047	November 30, 2005
B1048	January 31, 2006
B1050	January 31, 2006
B1051	January 31, 2006
B1052	January 31, 2006
B1053	January 31, 2006
B1054	January 31, 2006
B1055	January 31, 2006

B1065	June 30, 2006
B1082	May 31, 2007
B1184	June 30, 2009
B1185	June 30, 2009
B1186	June 30, 2009
B1187	June 30, 2009
B1188	June 30, 2009
B1189	June 30, 2009
B1097	June 30, 2007
B1098	June 30, 2007
B1213	November 1, 2009
B1214	November 1, 2009
B1216	November 1, 2009
B120553	August 8, 2009
B120650	August 8, 2009