



National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Melissa Madigan, Policy and Communications Director
DATE: October 15, 2009
RE: FDA Authorization for Use of Expired Tamiflu for Oral Suspension

NABP recently learned that pharmacists in some states are refusing to accept and dispense Tamiflu[®] from the Strategic National Stockpile because it is beyond its labeled expiration date. Please be advised, however, that Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for Oral Suspension as part of the federal government's response to the 2009 H1N1 Influenza public health emergency.

The lots of Tamiflu for Oral Suspension that have been authorized (see table below) are part of the Strategic National Stockpile and have been tested through the federal government's Shelf-Life Extension Program (SLEP). Under SLEP, FDA evaluates each lot to ensure the quality and stability of the product to determine if it is acceptable for use beyond its expiration date. Through this testing process, FDA has determined that data support the use of these lots of Tamiflu for Oral Suspension beyond their expiration dates.

Tamiflu for Oral Suspension: Lots Authorized for Use Beyond Original Expiry Date

<u>Lot Number</u>	<u>Manufacturer's Original Expiry Date</u>	<u>Date Supported by SLEP Testing</u>
B1184	June 30, 2009	May 31, 2011
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
B1045	May 31, 2005	February 28, 2010
B1046	November 30, 2005	February 28, 2010
B1047	November 30, 2005	February 28, 2010
B1048	January 31, 2006	August 31, 2010
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

Tamiflu for Oral Suspension: (continued)

<u>Lot Number</u>	<u>Manufacturer's Original Expiry Date</u>	<u>Date Supported by SLEP Testing</u>
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 lots of Tamiflu for Oral Suspension now authorized by FDA for use beyond their expiration dates are not required to be relabeled with information about the use of the products beyond their expiration dates. Therefore, health care professionals and patients might receive Tamiflu for Oral Suspension that is beyond its labeled expiration date. The boards of pharmacy are encouraged to reassure the pharmacists in their jurisdictions that they are authorized to dispense these products.

More information is available in the attached FDA documents:

- “Information for Healthcare Professionals – Authorization of Use of Expired Tamiflu for Oral Suspension”
- “Stockpiled Antivirals at or Nearing Expiration”
- FDA authorization letter to CDC, July 14, 2009

These documents, along with additional information on H1N1, are available on the FDA Web site via www.cdc.gov/h1n1flu/recommendations.htm.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary