U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

State Antiviral Drug Stockpile
HHS Update: February 11, 2020

HHS is aware that some states continue to retain stockpiles of antiviral drugs as part of influenza planning and response. Many of the drug lots held in state stockpiles have passed the manufacturer's labeled expiration date or the extended expiration dates previously provided to states. Updated information from FDA about extended expiration dating of stockpiled Tamiflu and Relenza products is provided below.

Expiration Dating: Use of Stockpiled Antivirals beyond the Labeled Expiration Date:

- **Tamiflu 75 mg capsules:** HHS is aware of Tamiflu product held in state stockpiles that has passed the labeled expiration date or the extended 10-year shelf life expiry previously communicated to states in March 2018.[1] Based on FDA's review of scientific data, FDA has concluded for emergency responses that, ***provided the products have been stored under labeled storage conditions, it is scientifically supportable for certain lots of Tamiflu 75 mg capsules held in strategic stockpiles to be used for a maximum of 15 years beyond their date of manufacture.*** FDA will not take enforcement action with regard to the storage or emergency use of these lots of Tamiflu capsules, provided that the products have been stored under labeled storage conditions. This extension applies only to Tamiflu 75 mg capsules; it does not apply to generic versions of oseltamivir.

  FDA is not requiring or recommending that stockpiled Tamiflu product be relabeled with the new use date. However, stakeholders that apply this extension to their stockpiled Tamiflu product should clearly note in their stockpiles that FDA has allowed for its extension (e.g., by placing a placard on the outside of a pallet or shipping box). In addition, if extended Tamiflu product is dispensed during an influenza emergency response, stakeholders should inform health care providers and recipients about this product's expiration dating extension.

- **Relenza inhalation powder:** HHS is aware of Relenza inhalation powder product in state stockpiles that has passed the labeled expiration date or the extended 7-year shelf life expiry communicated to states in June 2010.[2] Based on FDA's review of scientific data, FDA has concluded for emergency responses that, ***provided the products have been stored under***

[1] As background, FDA previously allowed for expiration dating extensions of stockpiled Tamiflu capsules in 2018 and 2010. As communicated by CDC on March 20, 2018, based on FDA's review of scientific data, FDA concluded that, provided the products had been stored under labeled storage conditions, it would be scientifically supportable for certain lots of Tamiflu capsules held in strategic stockpiles to be used for a maximum of 10 years beyond their date of manufacture. Prior to that, in June 2010, FDA concluded that, provided Tamiflu capsules had been stored under the labeled storage conditions, it would be scientifically supportable for certain lots of Tamiflu capsules held in strategic stockpiles to be used for a maximum of 7 years beyond their date of manufacture.

[2] As background, FDA concluded in June 2010 that, provided Relenza inhalation powder had been stored under the labeled storage conditions, it would be scientifically supportable for certain lots of Relenza inhalation powder held in strategic stockpiles to be used for a maximum of 7 years beyond their date of manufacture.

***labeled storage conditions, it is scientifically supportable for certain lots of Relenza inhalation powder held in strategic stockpiles to be used for a maximum of 10 years beyond their date of manufacture*.** FDA will not take enforcement action with regard to the storage or emergency use of these lots of Relenza, provided that the products have been stored under labeled storage conditions.

FDA is not requiring or recommending that stockpiled Relenza product be relabeled with the new use date. However, stakeholders that apply this extension to their stockpiled Relenza product should clearly note in their stockpiles that FDA has allowed for its extension (e.g., by placing a placard on the outside of a pallet or shipping box). In addition, if extended Relenza product is dispensed during an influenza emergency response, stakeholders should inform health care providers and recipients about this product's expiration dating extension.

Retaining or Disposing State Antiviral Drug Stockpiles:

- As antiviral drug products in state stockpile inventories approach or pass their labeled expiration dates, please verify whether these products have an expiration date that has been extended as communicated by the FDA above.

- States may contact their MCM Specialist or email preparedness@cdc.gov to confirm extended dates for antiviral drug inventories eligible for extension. To confirm extension dates, please provide the following information: drug name, NDC, strength, lot number and original manufacture date.

- HHS would like to reiterate the importance of retaining state antiviral stockpiles up to their extended expiration date if applicable. However, states may opt to properly discard stockpiled product if they are no longer able to hold it. Product should be discarded in accordance with normal pharmaceutical disposal and applicable state laws. Please review carefully the expiration date in accordance with the above guidance before discarding inventory.

- FDA will work with CDC and ASPR to communicate any future dating extensions if they become available based on scientific data.