DEPARTMENT OF HEALTH & HUMAN SERVICES



Administration for Strategic Preparedness and Response Washington, D.C. 20201

December 21, 2022

Dear Health Care Provider,

The Strategic National Stockpile (SNS) has retained stockpiles of antiviral drugs as part of pandemic influenza planning and response. With the unprecedented rise in seasonal influenza activity and high demand for oral antiviral drugs this season, SNS is providing federally held Tamiflu® stockpiles to support treatment of infection caused by seasonal influenza. The purpose of this letter is to inform you of important information about federally distributed Tamiflu® products.

Current lots of SNS-held Tamiflu® have exceeded the manufacturer's original labeled expiration dates. As a result, these products have undergone FDA review for expiration dating extension. Based on their review of scientific data, FDA has concluded for emergency responses that, provided the Tamiflu product has been stored under labeled storage conditions, it is scientifically supportable for certain lots of Tamiflu® 30mg, 45mg, and 75mg capsules held in the SNS to be used for a maximum of 20 years beyond their date of manufacture. This expiration dating extension applies only to SNS-provided Tamiflu® 30mg, 45mg, and 75mg capsules; it does not apply to oral Tamiflu® suspensions or generic versions of oseltamivir. Note that some, but not all, SNS-provided product may include language on the label stating, "FOR STRATEGIC NATIONAL STOCKILE USE ONLY" and/or may have 2 peel-off labels on one side of the bottle. The bottles will also show an expiration date that has already passed; these products have not been re-labeled with their new extended expiration date.

A list of SNS-held Tamiflu® lot numbers with their new extended expiration dates (including their corresponding NDC number) can be accessed on our website: Improving Access to Influenza Countermeasures for U.S. Jurisdictions (hhs.gov).

We are aware of Tamiflu product held in state stockpiles that has passed the labeled expiration date. Provided the products have been stored under labeled storage conditions, it is scientifically supportable for certain lots of Tamiflu 30mg, 45mg, and 75mg capsules held in strategic stockpiles to be used for a maximum of 20 years beyond their date of manufacture. For more information please also see Expiration Dating Extension | FDA. Each state is responsible for conveying the new extended expiration dates of the state-held products to health care professionals and recipients of the products.

An additional list of Tamiflu® lot numbers with their new extended expiration dates (including their corresponding NDC number) can be accessed at: lmproving Access to Influenza Countermeasures for U.S. Jurisdictions (hhs.gov).

Questions regarding the extended expiration dates of Tamiflu® should be directed to SNS.ops@hhs.gov.

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