DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Memorandum

Date: December 20, 2013

To: Robert Lewis, Director, Division of Preparedness and Response, U.S. Nuclear Regulatory Commission

From: Rosemary Roberts, MD, Director, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research, and
Luciana Borio, MD, Assistant Commissioner for Counterterrorism Policy

12/20/2013
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Subject: Expiration Dating of iOSAT (Potassium Iodide Tablets, 130 mg) in Eight (8) States

In November 2013, the U.S. Nuclear Regulatory Commission (NRC) notified FDA that eight (8) states—Connecticut, Delaware, Massachusetts, Maryland, New Jersey, New York, Ohio, and Vermont—that stockpile potassium iodide (KI) tablets will be receiving replacement KI tablets in 2014. The KI product that these states currently stockpile is iOSAT (Potassium Iodide Tablets, 130 mg), which has a labeled expiration date of February 2014. NRC stated that it plans to replace this iOSAT with ThyroSafe (Potassium Iodide Tablets, 65 mg) in the eight states, but the new ThyroSafe is not anticipated to be delivered to these states until approximately April 2014. Therefore, these states may be holding iOSAT past its manufacturer's labeled expiration date for several months as the only KI product available to their residents until NRC is able to provide the new ThyroSafe product. NRC asked FDA whether the currently stockpiled iOSAT in these eight states could be retained and used for several months past the manufacturer's labeled expiration date of February 2014 until the replacement ThyroSafe becomes available.

As stated in FDA's KI shelf life extension guidance for federal agencies and state and local governments, KI tablets are inherently stable, so long as they have been stored under labeled storage conditions.[1] Therefore, FDA has concluded that, provided the products have been stored under the iOSAT labeled storage conditions, it is scientifically supportable for the following lots

[1] U.S. Food and Drug Administration. *Guidance for Federal Agencies and State and Local Governments: Potassium Iodide Tablets and Shelf Life Extension*. March 2004. http://www.fda.gov/downloads/Drugs/.../Guidances/ucm080549.pdf. Page 4 of the guidance provides specific information on observations about KI tablet stability based on historical data. For example, "...[s]tability studies over many years have confirmed that none of the components of KI tablets, including the active ingredient, has any significant potential for chemical degradation or interaction with other components or with components of the container closure system when stored according to labeled directions. To date, the only observed changes during stability testing have been the failure of some batches of KI tablets to meet the USP S1 dissolution specification, Q=75 percent in 15 minutes. Some tablets tested required slightly longer than the specified time to achieve dissolution, but even in the case of a failure of this sort, the product would remain usable..."

of iOSAT stockpiled in Connecticut, Delaware, Massachusetts, Maryland, New Jersey, New York, Ohio, and Vermont to continue to be stockpiled and used for up to six (6) months after the February 2014 manufacturer's labeled expiration date until replacement ThyroSafe is provided to them by NRC: **iOSAT lots P03-4, P03-6, P03-8, and P03-9**.[2]

FDA requests that this memorandum regarding iOSAT nearing its February 2014 expiration date be communicated to the appropriate state and local planning officials in the eight states identified by NRC and listed above. In the event of the need to use this iOSAT during an actual emergency, it is expected that the appropriate state and local planning officials in the eight states will communicate to iOSAT recipients in those states that FDA has determined the product can be used up to six months past the February 2014 labeled expiration date.

FDA is not requiring or recommending that the iOSAT lots currently held by these eight states be relabeled with a new use date or other information. When the eight states receive their replacement ThyroSafe from NRC, they should properly dispose of the iOSAT lots listed above that are labeled with the February 2014 expiration date.

For questions related to this memorandum, please contact Brad Leissa at brad.leissa@fda.hhs.gov or Brooke Courtney at brooke.courtney@fda.hhs.gov.

[2] Section 564A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to extend the expiration dating of certain stockpiled medical countermeasures intended to support the nation's ability to protect the public health or military preparedness and effectiveness. Under Section 564A(b) of the FD&C Act, products with extended expiry will not be deemed unapproved, adulterated, or misbranded. An expiration date extension must be supported by an appropriate scientific evaluation that is conducted or accepted by FDA. This authority is limited to eligible products (as defined in FD&C Act Section 564A(a)) that are intended for use to prevent, diagnose, or treat a disease or condition involving a chemical, biological, radiological, or nuclear (CBRN) agent.