DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Memorandum

Date: September 5, 2013

To: Pfizer/Meridian Medical Technologies

From: Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, and Luciana Borio, MD, Assistant Commissioner for Counterterrorism Policy and Director, Office of Counterterrorism and Emerging Threats

Subject: DuoDote® (atropine and pralidoxime chloride injection) Auto-Injector Expiry Dating

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On August 27, 2013, you issued a Dear Healthcare Provider Letter regarding DuoDote auto-injector potential under-dosing or failure to activate. In the letter, you explained that "based on a review of product lots at its manufacturing site, Meridian personnel determined that a small number of DuoDote® Auto-Injectors are out of specification" and that "FDA is actively reviewing data related to DuoDote® performance beyond its labeled expiration date, and will provide additional information and guidance regarding expired product or product nearing its expiration date. Product beyond expiry should be held for the time being until further guidance can be provided by FDA."

In follow up to the letter, FDA requests that this memorandum regarding expired product or product nearing its expiration date be communicated to the wholesalers, healthcare professionals, and emergency personnel who received the August 27 letter. FDA is aware that the following lots of DuoDote are approaching expiration or have already passed their original expiry date (see table below). Based on FDA's review of scientific data, FDA has concluded that, provided the products have been stored under labeled storage conditions, it is scientifically supportable for lots of DuoDote listed in the following table to be used for an additional year (1 year) beyond the manufacturer's original labeled expiry date.

DuoDote product is used for organophosphorous nerve agent or insecticide poisoning. FDA authorizes, pursuant to Section 564A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the following lots of DuoDote to be stored or used for nerve agent poisoning up to one (1) year beyond the manufacturer's original labeled expiry date, provided that the products have been stored under the labeled storage conditions.[1] While Section 564A does not apply to product held

[1] Section 564A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to extend the shelf life 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

or used for insecticide poisoning, FDA will not take enforcement action with regard to the storage or use for insecticide poisoning of the following lots of DuoDote up to one (1) year beyond the manufacturer's original labeled expiry date, provided that the products have been stored under the labeled storage conditions.

FDA is not requiring or recommending that the identified lots be relabeled with the new use date.

DuoDote Auto-Injector Lots

Lot Number	Manufacturer's Original Expiry Date	New Use Date (up to 1 year beyond manufacturer's original expiry date)
9AE307	March 31, 2013	March 31, 2014
9AE356	March 31, 2013	March 31, 2014
9AE545	March 31, 2013	March 31, 2014
9AE548	May 31, 2013	May 31, 2014
9AE636	May 31, 2013	May 31, 2014
9AE645	June 30, 2013	June 30, 2014
9AE835	September 30, 2013	September 30, 2014

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.

(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, including a nerve agent. This authority does not extend to non-CBRN uses of products, such as insecticide poisoning uses, but, as noted, FDA will not take enforcement action with respect to such uses.