



Memorandum

Date: June 26, 2017

To: Civilian Emergency Response Entities

From: Luciana Borio, MD, Acting Chief Scientist

Subject: Expiry Dating Extension Update for AtroPen (atropine), CANA (diazepam), DuoDote, Morphine Sulfate, and Pralidoxime Chloride Auto-Injectors for Use in Nerve Agent Emergencies

On November 22, 2013, the U.S. Food and Drug Administration (FDA) posted on its website an alert regarding supply disruptions and potential expiration date extensions of certain nerve agent auto-injector products manufactured by Meridian Medical Technologies.¹ In follow up to the November 22 alert, FDA issued a memorandum on October 2, 2014, listing certain lots of AtroPen (atropine), CANA (diazepam), morphine sulfate, and pralidoxime chloride auto-injector products that, if properly stored, could be used for up to an additional year (1 year) beyond the manufacturer's original labeled expiry date.² On March 2, 2016, FDA issued a memorandum that replaced and provided an update to the information in the October 2, 2014, memorandum to mitigate potential shortages of these auto-injector products held by civilian emergency response entities (e.g., fire and emergency medical service (EMS) agencies, hospitals, etc.) while product manufacturing issues continued to be resolved.³

This memorandum replaces and provides an update to the March 2, 2016, memorandum by: (1) adding new lots of AtroPen (atropine), CANA (diazepam), and pralidoxime chloride auto-injectors; (2) providing updated expiry dates for certain lots of AtroPen (atropine), CANA (diazepam), DuoDote, and pralidoxime chloride auto-injectors; and (3) providing updates on certain lots of AtroPen (atropine) and morphine sulfate auto-injectors that are no longer eligible for expiry dating extensions and should be properly disposed of. All such lots are included in the following table.

¹ U.S. Food and Drug Administration. *FDA alerts health care providers and emergency responders of a potential extension of expiration dates for certain auto-injectors manufactured by Meridian Medical Technologies*. November 22, 2013. <http://www.fda.gov/Drugs/DrugSafety/ucm376367.htm>.

² U.S. Food and Drug Administration. *Expiry Dating Extension Update for AtroPen (atropine), CANA (diazepam), Morphine Sulfate, and Pralidoxime Chloride Auto-Injectors*. October 2, 2014. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM420224.pdf>.

³ U.S. Food and Drug Administration. *Expiry Dating Extension Update for AtroPen (atropine), CANA (diazepam), Morphine Sulfate, and Pralidoxime Chloride Auto-Injectors*. March 2, 2016. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM496442.pdf>. (Note: The web posting for the March 2, 2016, memorandum is dated April 15, 2016.)

Based on FDA’s review of scientific data, FDA has concluded that it is scientifically supportable for the lots of AtroPen (atropine), CANA (diazepam), DuoDote, and pralidoxime chloride auto-injectors listed in the following table to be used for nerve agent emergencies up to the identified new use dates, which are beyond the manufacturer’s original labeled expiry date, provided that the products have been – and continue to be – stored under the manufacturer’s labeled storage conditions.^{4,5} However, because no further expiry dating extensions of certain lots of AtroPen (atropine) and morphine sulfate auto-injectors identified below are possible, these lots are no longer useable and should be properly disposed of.

FDA is not requiring or recommending that the identified lots in the following table be relabeled with the new use date. When new AtroPen (atropine), CANA (diazepam), DuoDote, morphine sulfate, and pralidoxime chloride auto-injectors become available, FDA recommends that the following lots be replaced with the new product.

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.

⁴ 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.

⁵ On April 11, 2017, under section 564(b)(1)(C) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves nerve agents or certain insecticides (organophosphorus and/or carbamate).

**AtroPen (atropine), CANA (diazepam), DuoDote, and Pralidoxime Chloride
Auto-Injector Lots Eligible for Use for Nerve Agent Emergencies beyond the
Manufacturer's Original Labeled Expiration Date**

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
AtroPen (atropine)		
1PE860	November 30, 2014	November 30, 2017
1PF784	October 31, 2014	October 31, 2017
1PG783	October 31, 2014	October 31, 2017
2PE127	January 31, 2015	January 31, 2018
2PG115	January 31, 2015	January 31, 2018
2PG201	January 31, 2015	January 31, 2018
2PE729	September 30, 2015	September 30, 2018
2PF298	September 30, 2015	September 30, 2018
OSL616*	November 30, 2013*	* Previously, FDA provided extended expiry dates for the lots of AtroPen (atropine) auto-injectors marked with an asterisk (*). However, because no further expiry dating extensions of these lots are possible under this memorandum, these lots are no longer useable and should be properly disposed of.⁶
OSM801*	November 30, 2013*	
OS4468*	July 31, 2015*	
OS4637*	July 31, 2015*	
CANA (diazepam)		
8D1037	May 31, 2013	May 31, 2018
8D1038	May 31, 2013	May 31, 2018
8D1039	May 31, 2013	May 31, 2018
8D1366	May 31, 2013	May 31, 2018
8D1367	May 31, 2013	May 31, 2018
8D1368	May 31, 2013	May 31, 2018
9D1347	August 31, 2014	August 31, 2019
9D1666	July 31, 2014	July 31, 2019
9D1667	July 31, 2014	July 31, 2019
9DB731	August 31, 2014	August 31, 2019
9DY732	August 31, 2014	August 31, 2019
0D1093	December 31, 2014	December 31, 2019
0D1264	March 31, 2015	March 31, 2020
0D1460	April 30, 2015	April 30, 2020
0D1461	April 30, 2015	April 30, 2020
0D1462	April 30, 2015	April 30, 2020
1D1349	April 30, 2016	April 30, 2021

⁶ The following AtroPen (atropine) lots (with the original labeled expiry dates listed) also are no longer useable and should be properly disposed of: OSL357 (May 31, 2013); OSL358 (May 31, 2013); OSL619 (July 31, 2013); OSL620 (July 31, 2013); OSM286 (April 30, 2013); and OSM617 (July 31, 2013).

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
1D1520	May 31, 2016	May 31, 2021
1D1562	June 30, 2016	June 30, 2021
2D2698	August 31, 2017	August 31, 2022
2D2699	August 31, 2017	August 31, 2022
2D2700	August 31, 2017	August 31, 2022
2D2765	October 31, 2017	October 31, 2022
DuoDote		
8AE795	October 31, 2012	October 31, 2018
9AE306	January 31, 2013	January 31, 2019
9AE307	March 31, 2013	March 31, 2019
9AE356	March 31, 2013	March 31, 2019
9AE545	March 31, 2013	March 31, 2019
9AE548	May 31, 2013	May 31, 2019
9AE636	May 31, 2013	May 31, 2019
9AE645	June 30, 2013	June 30, 2019
9AE835	September 30, 2013	September 30, 2019
0AE158	December 31, 2013	December 31, 2019
0AE159	December 31, 2013	December 31, 2019
0AE287	February 28, 2014	February 28, 2020
0AE458	April 30, 2014	April 30, 2020
0AE500	May 31, 2014	May 31, 2020
0AE501	May 31, 2014	May 31, 2020
0AE792	September 30, 2014	September 30, 2020
1AE200	December 31, 2014	December 31, 2020
1AE201	February 28, 2015	February 28, 2021
1AE406	April 30, 2015	April 30, 2021
1AE502	March 30, 2015	March 30, 2021
1AE515	May 31, 2015	May 31, 2021
1AE516	June 30, 2015	June 30, 2021
1AE701	August 31, 2015	August 31, 2021
1AE702	September 30, 2015	September 30, 2021
1AE703	September 30, 2015	September 30, 2021
2AE752	October 31, 2016	October 31, 2022
Morphine Sulfate*		
2HD060*	February 28, 2014*	* Previously, FDA provided extended expiry dates for the lots of morphine sulfate auto-injectors marked with an asterisk (*). However, because no further expiry dating extensions of these lots are possible under this memorandum, these lots are no longer useable and should be properly disposed of.
2HD116*	February 28, 2014*	
2HD202*	February 28, 2014*	
2HJ452*	July 31, 2014*	
2HJ686*	August 31, 2014*	
2HJ687*	August 31, 2014*	
2HJ688*	August 31, 2014*	
2HJ689*	August 31, 2014*	
Pralidoxime Chloride		
9TF088	March 31, 2014	March 31, 2019

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
0TF265	March 31, 2015	March 31, 2020
1TF533	August 31, 2016	August 31, 2021