DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Memorandum

Date: November 18, 2019

To: Civilian Emergency Response Entities

From: RADM Denise Hinton, MS, BSN, 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

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Since 2013, the U.S. Food and Drug Administration (FDA) has posted on its website information regarding supply disruptions of certain nerve agent auto-injector products manufactured by Meridian Medical Technologies (MMT) and several memoranda and updates listing certain lots of AtroPen (atropine), CANA (diazepam), DuoDote, morphine sulfate, and pralidoxime chloride auto-injector products that, if properly stored, could be used for certain periods beyond the labeled expiration date.[1] The FDA messaging has focused on such auto-injector products held by civilian emergency response entities (e.g., fire and emergency medical service (EMS) agencies, hospitals, etc.) for use during nerve agent emergencies while product manufacturing issues continued to be resolved.

This memorandum replaces FDA's June 26, 2017, memorandum[2] and previous web postings[3] and provides updates on: (1) DuoDote auto-injector expiration dating extensions; (2) new expiration dates for certain lots of CANA (diazepam) and pralidoxime chloride auto-injectors; and (3) 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.

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[1] U.S. Food and Drug Administration (FDA). *FDA alerts health care providers and emergency responders of expiration date extensions of certain auto-injectors manufactured by Meridian Medical Technologies.* https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-providers-and-emergency-responders-expiration-date-extensions-certain-auto.

[2] FDA. *Memorandum: Expiry Dating Extension Update for AtroPen (atropine), CANA (diazepam), DuoDote, Morphine Sulfate, and Pralidoxime Chloride Auto-Injectors for Use in Nerve Agent Emergencies.* June 26, 2017. https://www.fda.gov/media/106033/download.

[3] FDA. *FDA alerts health care providers and emergency responders of expiration date extensions of certain auto-injectors manufactured by Meridian Medical Technologies.* https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-providers-and-emergency-responders-expiration-date-extensions-certain-auto.

DuoDote Auto-Injectors:

Lots with a labeled expiration date of May 2013-October 2016:

- Based on available scientific data, lots of DuoDote auto-injectors in the table below are not eligible for additional expiration dating extensions beyond the new use dates posted. As FDA has stated since 2014, if MMT provides replacement DuoDote product to stakeholders during the posted extension period, then it is expected that stakeholders holding the DuoDote lots in the following table will replace and properly dispose of them as soon as possible. MMT has informed FDA that it has fulfilled its commitment to replace DuoDote auto-injector units in the field with a labeled expiration date of May 2013 to October 2016.

- However, if stakeholders have not received replacement DuoDote product from MMT and still hold lots in the following table, then they may continue to apply the new use dates provided for those lots in the table below until the product is replaced or reaches the end of its new use date, after which it should be properly disposed of.

Lots with a labeled expiration date of February 2019 or later:

- In addition, FDA has received stakeholder inquiries about expiration dating extensions for certain lots of DuoDote product they have received from MMT since 2015 (i.e., with a labeled expiration date of February 2019 or later) and are not included in the table below. The DuoDote expiration dating extensions FDA previously issued were in response to supply disruptions. Because DuoDote manufacturing has resumed, expiration dating extensions of lots with a labeled expiration date of February 2019 or later are not warranted at this time.

For questions about DuoDote orders, stakeholders should contact Jonathan Daproza at Meridian Medical Technologies at jonathan.daproza@meridianmt.com (443-259-7878) or MMT's main email address (info@meridianmt.com) or phone number (443-259-7800).

CANA (diazepam) and Pralidoxime Chloride Auto-Injectors:

Based on FDA's review of scientific data, FDA has concluded that it is scientifically supportable for certain lots of CANA (diazepam) 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] FDA is not

[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 under this authority 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

requiring or recommending that these identified lots be relabeled with the new use date. If new CANA (diazepam) and pralidoxime chloride auto-injectors become available, FDA recommends that the following lots be replaced with the new product.

For certain CANA (diazepam) lots for which the "new use date" has already passed, FDA recommends that stakeholders retain the lots in the event that additional scientific information becomes available to support additional extensions. If additional scientific information does not support further extensions for a specific lot number, FDA will provide a future update.

AtroPen (atropine) and Morphine Sulfate Auto-Injectors:

The table below also includes 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.

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.

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).

Status of the Use of AtroPen (atropine), CANA (diazepam), DuoDote, and Pralidoxime Chloride Auto-Injector Lots 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)*		
2PE729*	September 30, 2015*	*** 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.**
2PF298*	September 30, 2015*	
OSM286*	April 30, 2013*	
OSL357*	May 31, 2013*	
OSL358*	May 31, 2013*	
OSM617*	July 31, 2013*	
OSL619*	July 31, 2013*	
OSL620*	July 31, 2013*	
0SL616*	November 30, 2013*	
0SM801*	November 30, 2013*	
1PE860*	November 30, 2014*	
1PF784*	October 31, 2014*	
1PG783*	October 31, 2014*	
2PE127*	January 31, 2015*	
2PG115*	January 31, 2015*	
2PG201*	January 31, 2015*	
0S4468*	July 31, 2015*	

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
0S4637*	July 31, 2015*	
CANA (diazepam)*		
8D1037*	May 31, 2013*	*** For CANA (diazepam) lots in this table for which the "new use date" has already passed, FDA recommends that stakeholders retain such lots in the event that FDA authorizes additional extensions.**
8D1038*	May 31, 2013*	
8D1039*	May 31, 2013*	
8D1366*	May 31, 2013*	
8D1367*	May 31, 2013*	
8D1368*	May 31, 2013*	
9D1347	August 31, 2014	August 31, 2020
9D1666	July 31, 2014	July 31, 2020
9D1667	July 31, 2014	July 31, 2020
9DB731	August 31, 2014	August 31, 2020
9DY732	August 31, 2014	August 31, 2020
0D1093	December 31, 2014	December 31, 2020
0D1264	March 31, 2015	March 31, 2021
0D1460	April 30, 2015	April 30, 2021
0D1461	April 30, 2015	April 30, 2021
0D1462	April 30, 2015	April 30, 2021
1D1349	April 30, 2016	April 30, 2022
1D1520	May 31, 2016	May 31, 2022

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
1D1562	June 30, 2016	June 30, 2022
2D2698	August 31, 2017	August 31, 2023
2D2699	August 31, 2017	August 31, 2023
2D2700	August 31, 2017	August 31, 2023
2D2765	October 31, 2017	October 31, 2023
DuoDote*		
8AE795*	October 31, 2012*	*** Previously, FDA provided extended expiry dates for the lots of DuoDote 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.**
9AE306*	January 31, 2013*	
9AE307*	March 31, 2013*	
9AE356*	March 31, 2013*	
9AE545*	March 31, 2013*	
9AE548*	May 31, 2013*	
9AE636*	May 31, 2013*	
9AE645*	June 30, 2013*	
9AE835*	September 30, 2013*	
0AE158	December 31, 2013	December 31, 2019
0AE159	December 31, 2013	December 31, 2019
0AE287	February 28, 2014	February 29, 2020
0AE458	April 30, 2014	April 30, 2020
0AE500	May 31, 2014	May 31, 2020

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
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 31, 2015	March 31, 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*	

Product/ Lot Number	Manufacturer's Original Expiry Date	New Use Date (beyond manufacturer's original expiry date)
2HJ689*	August 31, 2014*	
Pralidoxime Chloride		
9TF088	March 31, 2014	March 31, 2020
0TF265	March 31, 2015	March 31, 2021
1TF533	August 31, 2016	August 31, 2021