



Memorandum

Date: March 2, 2016

To: Civilian Emergency Response Entities

From: Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, and
Luciana Borio, MD, Acting Chief Scientist

Subject: Expiry Dating Extension Update for AtroPen (atropine), CANA (diazepam),
Morphine Sulfate, and Pralidoxime Chloride Auto-Injectors

On November 22, 2013, the Food and Drug Administration (FDA) posted on its website an alert regarding supply disruptions and potential expiration date extensions of certain 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 This memorandum replaces and provides an update to the information in the October 2 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 continue to be resolved.

Based on FDA's review of scientific data, FDA has concluded that it is scientifically supportable for the lots of AtroPen (atropine), CANA (diazepam), morphine sulfate, and pralidoxime chloride auto-injectors listed in the following table to be used up to the identified new use dates, which are beyond the manufacturer's original labeled expiry date. FDA will not take enforcement action with regard to the storage or use of these lots, provided that the products have been – and continue to be – stored under the manufacturer's labeled storage conditions.

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), 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.

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>.

**AtroPen (atropine), CANA (diazepam), Morphine Sulfate, and Pralidoxime Chloride
Auto-Injector Lots Eligible for Use 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)		
0SL616	November 30, 2013	May 31, 2015
0SM801	November 30, 2013	May 31, 2015
1PE860	November 30, 2014	November 30, 2016
1PF784	October 31, 2014	October 31, 2016
1PG783	October 31, 2014	October 31, 2016
2PE127	January 31, 2015	January 31, 2017
2PG115	January 31, 2015	January 31, 2017
2PG201	January 31, 2015	January 31, 2017
0S4468	July 31, 2015	January 31, 2017
0S4637	July 31, 2015	January 31, 2017
CANA (diazepam)		
9D1347	August 31, 2014	August 31, 2016
9D1666	July 31, 2014	July 31, 2016
9D1667	July 31, 2014	July 31, 2016
9DB731	August 31, 2014	August 31, 2016
9DY732	August 31, 2014	August 31, 2016
0D1093	December 31, 2014	December 31, 2016
0D1264	March 31, 2015	March 31, 2017
0D1460	April 30, 2015	April 30, 2017
0D1461	April 30, 2015	April 30, 2017
0D1462	April 30, 2015	April 30, 2017
Morphine Sulfate		
2HD060	February 28, 2014	February 29, 2016
2HD116	February 28, 2014	February 29, 2016
2HD202	February 28, 2014	February 29, 2016
2HJ452	July 31, 2014	July 31, 2016
2HJ686	August 31, 2014	August 31, 2016
2HJ687	August 31, 2014	August 31, 2016
2HJ688	August 31, 2014	August 31, 2016
2HJ689	August 31, 2014	August 31, 2016
Pralidoxime Chloride		
9TF088	March 31, 2014	March 31, 2016
0TF265	March 31, 2015	March 31, 2017