U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA alerts health care providers and emergency responders of expiration date extensions of certain auto-injectors manufactured by Meridian Medical Technologies

DuoDote, AtroPen, CANA, Morphine Sulfate, and Pralidoxime Chloride auto-injectors manufactured by Meridian Medical Technologies nearing or beyond their labeled or extended expiration dates should be retained until further guidance is provided by FDA.

[03/27/2015] FDA is alerting health care professionals and emergency responders of updated dates through which DuoDote auto-injectors, manufactured by Meridian Medical Technologies, may be used beyond the manufacturer's labeled expiration date. To help ensure patient safety, these products should have been — and should continue to be — stored as labeled.

This posting updates FDA's **May 13, 2014 alert (/Drugs/DrugSafety/ucm376367.htm)**, which notified health care professionals and emergency responders of a two-year extension of the labeled expiration dates of certain lots of DuoDote auto-injectors. The table below is an updated list of DuoDote auto-injector lots and new use dates. This new list, which replaces previously

13), and **September 5, 2013 memorandum (/downloads/Drugs/DrugSafety/UCM376385.pdf)**, as well as 10 new lots.

FDA is not requiring or recommending that the identified lots in the following table be relabeled with their new use dates. However, if replacement DuoDote product becomes available during the extension period, then it is expected that the DuoDote lots in this updated table will be replaced and properly disposed of as soon as possible.

Please contact Brad Leissa at **brad.leissa@fda.hhs.gov (mailto:brad.leissa@fda.hhs.gov)** or Brooke Courtney at **brooke.courtney@fda.hhs.gov (mailto:brooke.courtney@fda.hhs.gov)** with questions regarding this table.

DuoDote auto-injector lots eligible for use beyond the manufacturer's labeled expiration date (updated March 27, 2015).

Lot Number	Manufacturer's Original Expiry Date	New Use Date
8AE795	October 31, 2012	October 31, 2015
9AE306	January 31, 2013	January 31, 2016
9AE307	March 31, 2013	March 31, 2016
9AE356	March 31, 2013	March 31, 2016
9AE545	March 31, 2013	March 31, 2016
9AE548	May 31, 2013	May 31, 2016
9AE636	May 31, 2013	May 31, 2016
9AE645	June 30, 2013	June 30, 2016
9AE835	September 30, 2013	September 30, 2016
0AE158	December 31, 2013	December 31, 2016
0AE159	December 31, 2013	December 31, 2016
0AE287	February 28, 2014	February 28, 2017
0AE458	April 30, 2014	April 30, 2017
0AE500	May 31, 2014	May 31, 2017
0AE501	May 31, 2014	May 31, 2017
0AE792	September 30, 2014	September 30, 2017
1AE200	December 31, 2014	December 31, 2017
1AE201	February 28, 2015	February 28, 2018
1AE406	April 30, 2015	April 30, 2018
1AE502	March 30, 2015	March 30, 2018
1AE515	May 31, 2015	May 31, 2018
1AE516	June 30, 2015	June 30, 2018
1AE701	August 31, 2015	August 31, 2018
1AE702	September 30, 2015	September 30, 2018

1AE703	September 30, 2015	September 30, 2018
2AE752	October 31, 2016	October 31, 2019

[10/24/2014] FDA is alerting health care professionals and emergency responders that specific lots of AtroPen (atropine), CANA (diazepam), morphine sulfate, and pralidoxime chloride auto-injectors manufactured by Meridian Medical Technologies can be used for up to one additional year beyond the manufacturer's labeled expiration date.

This notice is in follow up to FDA's November 22, 2013, statement, and will help mitigate potential shortages of these medically necessary drugs.

To help assure patient safety, products should have been − and should continue to be − stored under the manufacturer's labeled storage conditions.

The list of lots of these four products that can be used for up to an additional year beyond the manufacturer's labeled expiration date can be found in FDA's **October 2, 2014, memorandum (/downloads/Drugs/DrugSafety/UCM420224.pdf)**.

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FDA further extends expiration dates of DuoDote auto-injector lots manufactured by Meridian Medical Technologies

[05/13/2014] FDA is alerting health care professionals and emergency responders that two more lots (8AE795 and 9AE306) of DuoDote auto-injectors, manufactured by Meridian Medical Technologies, can be used for up to two years beyond the manufacturer's labeled expiration date. To help ensure patient safety, these products should have been — and should continue to be — stored under their labeled storage conditions.

This updates FDA's **March 28, 2014 alert**, which notified health care professionals and emergency responders of a two-year extension of the labeled expiration date of certain lots of DuoDote auto-injectors. The table below is an updated list of DuoDote auto-injector lots and new use dates. This

ugSafety/UCM376385.pdf); and also includes the two new lots.

DuoDote auto-injector lots eligible for use up to two years beyond the manufacturer's labeled expiration date (updated May 13, 2014).

Lot Number	Manufacturer's Original Expiry Date	New Use Date (up to 2 years beyond manufacturer's original expiry date)
8AE795	October 31, 2012	October 31, 2014

Lot Number	Manufacturer's Original Expiry Date	New Use Date (up to 2 years beyond manufacturer's original expiry date)
9AE306	January 31, 2013	January 31, 2015
9AE307	March 31, 2013	March 31, 2015
9AE356	March 31, 2013	March 31, 2015
9AE545	March 31, 2013	March 31, 2015
9AE548	May 31, 2013	May 31, 2015
9AE636	May 31, 2013	May 31, 2015
9AE645	June 30, 2013	June 30, 2015
9AE835	September 30, 2013	September 30, 2015
0AE158	December 31, 2013	December 31, 2015
0AE159	December 31, 2013	December 31, 2015
0AE287	February 28, 2014	February 28, 2016
0AE458	April 30, 2014	April 30, 2016
0AE500	May 31, 2014	May 31, 2016
0AE501	May 31, 2014	May 31, 2016
0AE792	September 30, 2014	September 30, 2016

If replacement DuoDote product becomes available during the two-year extension period, then it is expected that the DuoDote lots in this updated table will be replaced and properly disposed of as soon as possible.

FDA is not requiring or recommending that the identified lots be relabeled with the new use date. Please contact Brad Leissa at **brad.leissa@fda.hhs.gov (mailto:brad.leissa@fda.hhs.gov)** or Brooke Courtney at **brooke.courtney@fda.hhs.gov (mailto:brooke.courtney@fda.hhs.gov)** with questions regarding this table.

[03/28/2014] FDA is alerting health care professionals and emergency responders that certain lots of DuoDote auto-injectors, manufactured by Meridian Medical Technologies, can be used for up to two years beyond the manufacturer's labeled expiration date. To help ensure patient safety, these products should have been — and should continue to be — stored under their labeled storage conditions.

This updates FDA's **December 2013 alert (http://www.fda.gov/Drugs/DrugSafety/ucm376367.htm#december2013)**, which notified health care professionals and emergency responders of a one-year extension of the labeled expiration date of certain lots of DuoDote auto-injectors. The table below is an updated list of DuoDote auto-injector lots and new use dates. This new list includes each of the lots listed in FDA's **September 76367.htm)**[2], and also includes one new lot, 0AE792.

DuoDote auto-injector lots eligible for use up to two years beyond the manufacturer's labeled expiration date (updated March 28, 2014).

Lot Number	Manufacturer's Original Expiry Date	New Use Date (up to 2 years beyond manufacturer's original expiry date)
9AE307	March 31, 2013	March 31, 2015
9AE356	March 31, 2013	March 31, 2015
9AE545	March 31, 2013	March 31, 2015
9AE548	May 31, 2013	May 31, 2015
9AE636	May 31, 2013	May 31, 2015
9AE645	June 30, 2013	June 30, 2015
9AE835	September 30, 2013	September 30, 2015
0AE158	December 31, 2013	December 31, 2015
0AE159	December 31, 2013	December 31, 2015
0AE287	February 28, 2014	February 28, 2016
0AE458	April 30, 2014	April 30, 2016
0AE500	May 31, 2014	May 31, 2016
0AE501	May 31, 2014	May 31, 2016
0AE792	September 30, 2014	September 30, 2016

If replacement DuoDote product becomes available during the two-year extension period, then it is expected that the DuoDote lots in this updated table will be replaced and properly disposed of as soon as possible.
FDA is not requiring or recommending that the identified lots be relabeled with the new use date.
Please contact Brad Leissa at **brad.leissa@fda.hhs.gov (mailto:brad.leissa@fda.hhs.gov)** or Brooke Courtney at **brooke.courtney@fda.hhs.gov (mailto:brooke.courtney@fda.hhs.gov)** with questions regarding this table.

[12/24/2013] FDA is now alerting health care providers and emergency responders of more lots of DuoDote auto-injectors, manufactured by Meridian Medical Technologies, a Pfizer, Inc., company, that can be used for up to an additional year past the manufacturer's labeled expiration date. To help assure patient safety, products should have been stored under labeled storage conditions.

cm376367.htm), the following table is a cumulative list of DuoDote lots listed in FDA's **September 5, 2013, memorandum (/downloads/Drugs/DrugSafety/UCM376385.pdf)** and additional lots identified by FDA in December 2013 to further address stakeholder needs.

For questions related to this table, please contact Brad Leissa at **brad.leissa@fda.hhs.gov (mailto:brad.leissa@fda.hhs.gov)** or Brooke Courtney at **brooke.courtney@fda.hhs.gov (mailto:brooke.courtney@fda.hhs.gov)**.

DuoDote auto-injector lots eligible for use up to one year beyond the manufacturer's labeled expiration date (updated December 24, 2013)

	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
0AE158	December 31, 2013	December 31, 2014
0AE159	December 31, 2013	December 31, 2014
0AE287	February 28, 2014	February 28, 2015
0AE458	April 30, 2014	April 30, 2015
0AE500	May 31, 2014	May 31, 2015
0AE501	May 31, 2014	May 31, 2015

FDA alerts health care providers and emergency responders of a potential extension of expiration dates for certain auto-injectors manufactured by Meridian Medical Technologies

[11/22/2013] The U.S. Food and Drug Administration is aware of a disruption in supply to health care providers and emergency response personnel of Atropen (atropine), DuoDote (atropine/pralidoxime chloride), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors manufactured by Meridian Medical Technologies, a Pfizer Inc. company. FDA and Meridian are working together to resolve the disruption as quickly as possible, but it is unclear how long this disruption may persist.

As communicated on **September 5, 2013 (PDF - 39KB) (/downloads/Drugs/DrugSafety/UCM376385.pdf)**, FDA concluded that it was scientifically supported that certain lots of DuoDote can be used for an additional year beyond the manufacturer's original labeled expiration date. FDA is continuing to assess whether these identified lots of DuoDote can receive further expiration date extensions if needed, and whether additional lots of DuoDote that were not listed in FDA's September 5, 2013, memo can have their expiration date extended.

FDA is currently reviewing data for the potential use of Atropen (atropine), DuoDote (atropine/pralidoxime chloride), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors beyond their labeled expiration dates in order to mitigate any potential shortages of these medically necessary drugs. Products nearing or beyond their labeled expiration dates **should be retained** until further guidance is provided by FDA.

What health care providers and emergency response personnel should know:

- Health care providers and emergency response personnel who have any of the auto-injectors manufactured by Meridian identified above that are nearing or beyond the labeled expiration date should retain the products until FDA is able to provide additional information regarding the continued use of these products.
- Due to medical necessity and potential drug shortages, FDA is reviewing data for the potential use of these products beyond their labeled expiration dates.
- FDA will provide additional information about use of these products beyond the labeled expiration date in the coming weeks. Until FDA provides additional information, these expired auto-injectors may be used for patient care under emergency situations when no other product is available.
- Health care providers and emergency response personnel should maintain and monitor these products under the storage conditions described in the product labeling information.
- FDA continues to work with Meridian to resolve manufacturing issues.
- It is unclear at this time when Meridian will have additional inventory of these auto-injectors available.

If health care providers and emergency response personnel have additional questions about these auto-injectors, please contact Meridian's customer service office at 1-866-478-6277.

FDA asks health care providers and consumers to report any adverse events that are associated with the use of any of these products to either Pfizer Safety (1-800-438-1985) or to the **FDA's MedWatch Adverse Event Reporting (http://www.fda.gov/medwatch)** program by:

- completing and submitting the report online at **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**; or

- downloading and completing the **form ()**, then submitting it via fax at 1-800-FDA-0178.

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