Meridian Medical Technologies Auto-Injectors: Extension of Expiration Dates

including Auto-Injectors for

Atropen (atropine)
DuoDote (atropine/pralidoxime chloride)
morphine sulfate
pralidoxime chloride
diazepam

AUDIENCE: Emergency Medicine, Pharmacy

ISSUE: FDA 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.

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.

RECOMMENDATIONS: 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 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.

Read the Medwatch safety alert, including links to the FDA statement and memo to Pfizer/Meridian, at: