



OHIO DEPARTMENT
OF PUBLIC SAFETY
SAFETY • SERVICE • PROTECTION

- Bureau of Motor Vehicles
- Emergency Management Agency
- **Emergency Medical Services**
- Office of Criminal Justice Services
- Ohio Homeland Security
- Ohio State Highway Patrol



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EMS Leaders:

In response to major concerns from emergency providers, the FDA has worked with Pfizer to extend the manufacturer's expiration dates on 4 types of emergency medications. The details are below and attached.

This will assist in the emergency management of the shortage of these three medicines.

It allows us to ask for FDA assistance in the future related to critical drug shortages

It will be a short time savings, because the replacement costs of these medications is going to be significantly higher. This week, the price of a single 1 mg vial of epinephrine 1:1000, is over \$17.

The FDA resource page below is a good reference.

A suggested action plan:

- Read the attached document so that you understand the elements of this extension program, and can explain them to your field personnel and pharmacists.
- Please contact your logistics staff today regarding the extension of expiration dates on these lots of medications. The FDA letter suggests NOT writing this on the drug container, so another way will need to be crafted to allow your personnel to understand the extension.
- Please print off a copy of the FDA notice for your reference, and use with any of your regulatory bodies.
- Advise all necessary personnel regarding these medications, but that the process, at this point, has not been extended to other medications.
- Rotate medications in an attempt to use those medicines closest to their expiration dates.

Thanks to all of you,

Jim Augustine, MD

Mission Statement

"to save lives, reduce injuries and economic loss, to administer Ohio's motor vehicle laws and to preserve the safety and well being of all citizens with the most cost-effective and service-oriented methods available."

THE FDA LANGUAGE

In addition, certain lots of emergency syringes have had their use dates extended based on stability data provided by Pfizer and reviewed by FDA, so that healthcare professionals can continue to use these specific lots during the shortage. The information about the specific lots with extended use dates is found in [these tables](#).

- Atropine Sulfate Injection, USP 0.1 mg/mL; 5 mL ABBOJECT syringe (NDC 0409-4910-34)
- Atropine Sulfate Injection, USP 0.1 mg/mL; 10 mL ABBOJECT syringe (NDC 0409-4911-34)
- Dextrose 50% Injection, USP, 50 mL ABBOJECT Syringe (NDC 0409-4902-34)
- Epinephrine Injection, USP 0.1 mg/mL; 10 mL ABBOJECT syringe (NDC 0409-4921-34)

FDA is not requiring or recommending that the identified lots in the referenced tables be relabeled with their new use dates. However, if replacement product becomes available during the extension period, then the agency expects that the lots in the referenced tables will be replaced and properly disposed of as soon as possible.

We will update the public as the situation changes. Continue to visit the [drug shortages webpage](#) for more information on approved sources of these drug products. For additional information, health care professionals can also contact Pfizer directly.

Please contact CDER Drug Shortage Staff at drugshortages@fda.hhs.gov with questions regarding these tables.

Extended Use Dates Provided by Pfizer to Assist with Emergency Syringe Shortages

[6-15-2017]

Due to the ongoing critical shortages of injectable drugs used in critical care, FDA is alerting health care professionals and emergency responders of updated dates through which some of these injectable drugs, manufactured by Hospira Inc, a Pfizer company, 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 per labeled conditions.

Hospitals that have the following lot numbers in stock will be able to use them through the corresponding new use dates to help with supply. As data on additional emergency syringe products and lot numbers become available, this list can be expanded.

Further information is found [here](#), and below.

FDA updates on Pfizer drug shortages

[6/15/17] The U.S. Food and Drug Administration is aware of the ongoing shortage situation affecting several injectable drugs, manufactured by Hospira, a Pfizer company, including [sodium bicarbonate injection](#) (vials and syringes), [dextrose 50% injection](#) (vials and syringes), as well as emergency syringes of other drugs, including [epinephrine](#), [calcium chloride](#) and [atropine sulfate](#). Pfizer has reported this shortage is caused by manufacturing, distribution and third party delays.

We are working closely with Pfizer to resolve these critical shortages by addressing the underlying causes. The agency is working to relieve these shortages through a variety of measures, including finding alternative manufacturers of these drug products. FDA continues to explore [all available options](#), which may include expediting review of applications or other submissions, or considering temporary regulatory flexibility for alternative sources.

In addition, certain lots of emergency syringes have had their use dates extended based on stability data provided by Pfizer and reviewed by FDA, so that healthcare professionals can continue to use these specific lots during the shortage. The information about the specific lots with extended use dates is found in [these tables](#).

- Atropine Sulfate Injection, USP 0.1 mg/mL; 5 mL ABBOJECT syringe (NDC 0409-4910-34)
- Atropine Sulfate Injection, USP 0.1 mg/mL; 10 mL ABBOJECT syringe (NDC 0409-4911-34)
- Dextrose 50% Injection, USP, 50 mL ABBOJECT Syringe (NDC 0409-4902-34)
- Epinephrine Injection, USP 0.1 mg/mL; 10 mL ABBOJECT syringe (NDC 0409-4921-34)

FDA is not requiring or recommending that the identified lots in the referenced tables be relabeled with their new use dates. However, if replacement product becomes available during the extension period, then the agency expects that the lots in the referenced tables will be replaced and properly disposed of as soon as possible.

We will update the public as the situation changes. Continue to visit the [drug shortages webpage](#) for more information on approved sources of these drug products. For additional information, health care professionals can also contact Pfizer directly.

Please contact CDER Drug Shortage Staff at drugshortages@fda.hhs.gov with questions regarding these tables.

Product and lot numbers of Atropine Sulfate Injection, Dextrose 50% Injection, and Epinephrine Injection products in ABBOJECT syringes eligible for use beyond the manufacturer’s labeled expiration date (as of June 15, 2017).

Atropine Sulfate Injection, USP 0.1 mg/mL; 5 mL ABBOJECT syringe (NDC 0409-4910-34)

| Product/ Lot Number | Manufacturer’s Original Expiry Date | New Use Date (beyond manufacturer’s original expiry date) |
|--------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| 51013DK00 | 1-Mar-2017 | 1-Sep-2017 |
| 52408DK00 | 1-Apr-2017 | 1-Oct-2017 |
| 54322DK00 | 1-Jun-2017 | 1-Dec-2017 |
| 54373DK00 | 1-Jun-2017 | 1-Dec-2017 |
| 54424DK00 | 1-Jun-2017 | 1-Dec-2017 |
| 58236DK00 | 1-Oct-2017 | 1-Apr-2018 |

Atropine Sulfate Injection, USP 0.1 mg/mL; 10 mL ABBOJECT syringe (NDC 0409-4911-34)

| Product/ Lot Number | Manufacturer’s Original Expiry Date | New Use Date (beyond manufacturer’s original expiry date) |
|--------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| 51475DK00 | 1-Mar-2017 | 1-Mar-2018 |

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| 52302DK00 | 1-Apr-2017 | 1-Apr-2018 |
| 52390DK00 | 1-Apr-2017 | 1-Apr-2018 |
| 52391DK00 | 1-Apr-2017 | 1-Apr-2018 |
| 53120DK00 | 1-May-2017 | 1-May-2018 |
| 53122DK00 | 1-May-2017 | 1-May-2018 |
| 53123DK00 | 1-May-2017 | 1-May-2018 |
| 53434DK00 | 1-May-2017 | 1-May-2018 |
| 53458DK00 | 1-May-2017 | 1-May-2018 |
| 54018DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54019DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54025DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54323DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54324DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54364DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 56053DK00 | 1-Aug-2017 | 1-Aug-2018 |
| 57032DK00 | 1-Sep-2017 | 1-Sep-2018 |
| 57033DK00 | 1-Sep-2017 | 1-Sep-2018 |
| 57034DK00 | 1-Sep-2017 | 1-Sep-2018 |
| 57035DK00 | 1-Sep-2017 | 1-Sep-2018 |

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| 58004DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 58006DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 58007DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 58424DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 58425DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 59039DK00 | 1-Nov-2017 | 1-Nov-2018 |
| 59051DK00 | 1-Nov-2017 | 1-Nov-2018 |
| 59052DK00 | 1-Nov-2017 | 1-Nov-2018 |
| 59384DK00 | 1-Nov-2017 | 1-Nov-2018 |

Dextrose 50% Injection, USP, 50 mL ABBOJECT Syringe (NDC 0409-4902-34)

| Product/ Lot Number | Manufacturer's Original Expiry Date | New Use Date (beyond manufacturer's original expiry date) |
|--------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| 49368DK00 | 1-Jan-2017 | 1-Jan-2018 |
| 52121DK00 | 1-Apr-2017 | 1-Apr-2018 |
| 52411DK00 | 1-Apr-2017 | 1-Apr-2018 |
| 53167DK00 | 1-May-2017 | 1-May-2018 |
| 53168DK00 | 1-May-2017 | 1-May-2018 |
| 54084DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54085DK00 | 1-Jun-2017 | 1-Jun-2018 |

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| 54089DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54090DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54329DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54330DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54356DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54361DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 54402DK00 | 1-Jun-2017 | 1-Jun-2018 |
| 55177DK00 | 1-Jul-2017 | 1-Jul-2018 |
| 55178DK00 | 1-Jul-2017 | 1-Jul-2018 |
| 56025DK00 | 1-Aug-2017 | 1-Aug-2018 |
| 56160DK00 | 1-Aug-2017 | 1-Aug-2018 |
| 56162DK00 | 1-Aug-2017 | 1-Aug-2018 |
| 58131DK00 | 1-Oct-2017 | 1-Oct-2018 |
| 59027DK00 | 1-Nov-2017 | 1-Nov-2018 |

Epinephrine Injection, USP 0.1 mg/mL; 10 mL ABBJECT syringe (NDC 0409-4921-34)

| Product/ Lot Number | Manufacturer's Original Expiry Date | New Use Date (beyond manufacturer's original expiry date) |
|--------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| 52002DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52004DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52005DK00 | 1-Jan-2017 | 1-Oct-2017 |

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| 52006DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52071DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52396DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52427DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 52461DK00 | 1-Jan-2017 | 1-Oct-2017 |
| 53115DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53116DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53117DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53118DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53144DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53182DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53423DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53424DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53425DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 53438DK00 | 1-Feb-2017 | 1-Nov-2017 |
| 54021DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54022DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54027DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54028DK00 | 1-Mar-2017 | 1-Dec-2017 |

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| 54118DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54201DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54202DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54327DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54328DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54377DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54421DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 54439DK00 | 1-Mar-2017 | 1-Dec-2017 |
| 55002DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55003DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55087DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55097DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55098DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55099DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55286DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55311DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55312DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55364DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55365DK00 | 1-Apr-2017 | 1-Jan-2018 |

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| 55377DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 55378DK00 | 1-Apr-2017 | 1-Jan-2018 |
| 56002DK00 | 1-May-2017 | 1-Feb-2018 |
| 56003DK00 | 1-May-2017 | 1-Feb-2018 |
| 56004DK00 | 1-May-2017 | 1-Feb-2018 |
| 56005DK00 | 1-May-2017 | 1-Feb-2018 |
| 56080DK00 | 1-May-2017 | 1-Feb-2018 |
| 56085DK00 | 1-May-2017 | 1-Feb-2018 |
| 56086DK00 | 1-May-2017 | 1-Feb-2018 |
| 56087DK00 | 1-May-2017 | 1-Feb-2018 |
| 56088DK00 | 1-May-2017 | 1-Feb-2018 |
| 56089DK00 | 1-May-2017 | 1-Feb-2018 |
| 56090DK00 | 1-May-2017 | 1-Feb-2018 |
| 56173DK00 | 1-May-2017 | 1-Feb-2018 |
| 56174DK00 | 1-May-2017 | 1-Feb-2018 |
| 56175DK00 | 1-May-2017 | 1-Feb-2018 |
| 57037DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57038DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57039DK00 | 1-Jun-2017 | 1-Mar-2018 |

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| 57046DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57178DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57179DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57180DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57242DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57421DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57422DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 57457DK00 | 1-Jun-2017 | 1-Mar-2018 |
| 58033DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58034DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58035DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58036DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58041DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58042DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58047DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58048DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58151DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58152DK00 | 1-Jul-2017 | 1-Apr-2018 |
| 58428DK00 | 1-Jul-2017 | 1-Apr-2018 |

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| 59043DK00 | 1-Aug-2017 | 1-May-2018 |
| 62359DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62360DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62404DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62405DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62406DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62407DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62409DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62414DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62415DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62416DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62417DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62447DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 62485DK00 | 1-Nov-2017 | 1-Aug-2018 |
| 63161DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63162DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63163DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63164DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63173DK00 | 1-Dec-2017 | 1-Sep-2018 |

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| 63175DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63180DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63263DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63264DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63265DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63266DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63267DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63294DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63295DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63296DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63297DK00 | 1-Dec-2017 | 1-Sep-2018 |
| 63393DK00 | 1-Dec-2017 | 1-Sep-2018 |