# Rural Health Center - SWOSU College of Pharmacy logo with windmill and line for wind

## RURAL ROCKS

[RECALLS](#_Toc459097188)

[ PharmaTech LLC Issues Voluntary Nationwide Recall Due to Potential Risk of Product Contamination](#_Toc459097189)

[SHORTAGES](#_Toc459097190)

[ Current and resolved drug shortages and discontinuations reported to the FDA - July 6, 2016](#_Toc459097191)

[DRUG](#_Toc459097192)

[ FDA Approves New GLP-1 Receptor Agonist Adlyxin for Diabetes](#_Toc459097193)

[ FDA approves Lupin’s generic Klor-Con August 11, 2016](#_Toc459097194)

[ Generic Dexedrine from Mylan Now Available](#_Toc459097195)

[HOSPITAL](#_Toc459097196)

[ CMS star ratings sneak peek shows rating system favors smaller hospitals with lower-risk patients](#_Toc459097197)

[ Micro-hospital' model could help underserved populations](#_Toc459097198)

[FDA](#_Toc459097199)

[ Latest Drug Safety Podcast](#_Toc459097200)

[ 3 Federal Regulatory Changes Affecting Pharmacy](#_Toc459097201)

[ Your Child's First Vaccines](#_Toc459097202)

[ Regulatory Reconnaissance](#_Toc459097203)

[ FDA Announces Major Change in Pharmacy Inspections](#_Toc459097204)

[ APhA Responds to FDA Draft Compounding Guidances](#_Toc459097205)

[ Draft Guidance Documents Seek to Restrict Compounders from Making Copies of Commercially Available Drugs](#_Toc459097206)

[IMMUNIZATIONS](#_Toc459097207)

[ Current Vaccine Shortages & Delays](#_Toc459097208)

[INSURANCE](#_Toc459097209)

[ Insurers restricting high-risk opioid users to select pharmacies](#_Toc459097210)

[ CMS Proposes Sweeping 'Episode Payment Models' for Cardiac Care, Hip/Femur Fracture Cases, Plus Changes to 'Comprehensive Care for Joint Replacement' Model](#_Toc459097211)

[ Medicare Advantage Value-Based Insurance Design Model](#_Toc459097212)

[NEWS](#_Toc459097213)

[ Pedal Away From Type 2 Diabetes - Study finds biking may help adults avoid the blood sugar disorder](#_Toc459097214)

[ Dietary Mineral Could Be One Key to Blood Pressure Control by: Jonathan Goodman - June 28, 2016](#_Toc459097215)

[ Survivors of Adult-onset Cancer Treated With Cisplatin Should Have Routine Auditory Exams](#_Toc459097216)

[ Tools to make your headache visits more efficient](#_Toc459097217)

[ Could CoQ10 Benefit Heart Failure Patients?](#_Toc459097218)

[ Retail 2027](#_Toc459097219)

[ Obesity May Be Bad for the Brain, Too](#_Toc459097220)

[ Study: Meat and Sugar Contribute Equally to Obesity](#_Toc459097221)

[ DASH Diet May Help To Prevent Gout Flares](#_Toc459097222)

[ Could Eating More Nuts Reduce Inflammation?](#_Toc459097223)

[ Heater-Cooler Devices](#_Toc459097224)

[ Guest blog: More members of Congress pressure Medicare on DIR fees](#_Toc459097225)

[ Fake Xanax Cut With Potent Pain Med Can Be a Killer](#_Toc459097226)

# RECALLS

## PharmaTech LLC Issues Voluntary Nationwide Recall Due to Potential Risk of Product Contamination

<http://www.fda.gov/Safety/Recalls/ucm515610.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 08/08/2016 | [Multiple brands](http://www.fda.gov/Safety/Recalls/ucm515610.htm)   | Liquid Drug Products   | Due to potential Burkholderia cepacia contamination | PharmaTech, LLC |
| 08/05/2016 | [Hospira](http://www.fda.gov/Safety/Recalls/ucm515199.htm)   | 0.25% BUPIVACAINE HYDROCHLORIDE INJECTION, USP   | Due to the presence of particulate matter | Hospira |
| 08/02/2016 | [Teva Pharmaceuticals](http://www.fda.gov/Safety/Recalls/ucm514656.htm)   | Amikacin Sulfate Injection USP   | Due to potential contamination with glass particulate matter | Teva Pharmaceuticals |
| 08/01/2016 | [Comfort Shield](http://www.fda.gov/Safety/Recalls/ucm514358.htm)   | Barrier Cream Cloths   | Due to product contamination with Burkholderia cepacia | Sage Products |
| 07/21/2016 | [Talon Compounding Pharmacy (TCP)](http://www.fda.gov/Safety/Recalls/ucm512680.htm)   | HCG and Sermorelin   | Lack of sterility assurance | Talon Compounding Pharmacy (TCP) |
| 07/15/2016 | [Rugby](http://www.fda.gov/Safety/Recalls/ucm511525.htm)   | Diocto Liquid, docusate sodium solution   | Burkholderia cepacia contamination | PharmaTech LLC |

# SHORTAGES

## Current and resolved drug shortages and discontinuations reported to the FDA - July 6, 2016

\*Note: Only those vaccines included on the recommended childhood and adolescent immunization schedule are included in this update.

Vaccines are listed in order used for the Childhood and Adolescent Immunization Schedule.

### National Vaccine Supply Shortages

| **Vaccine** | **Shortage** | **Temporary Change From Routine Recommendation** |
| --- | --- | --- |
| Hepatitis B | No |   |
| Rotavirus | No |   |
| Diphtheria, Tetanus, & Pertussis (DTaP and Tdap) | See [note 2](http://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html#note2) | See [current information about Pentacel[4 pages]](http://www.cdc.gov/vaccines/hcp/clinical-resources/downloads/pentacel-delay.pdf) Dec 2015 |
| Td | No |   |
| Haemophilus influenzae type B (Hib) | No  |   |
| Pneumococcal Conjugated (PCV) | No |   |
| Pneumococcal Polysaccharide (PPV) | No |   |
| Inactivated Polio (IPV) | No |   |
| Measles, Mumps, & Rubella (MMR) | See [note 1](http://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html#note1)  | See [Q&As about monovalent M-M-R vaccines](http://www.cdc.gov/vaccines/hcp/clinical-resources/mmr-faq-12-17-08.html) Oct 2009 |
| Influenza | No | See current information about [influenza](http://www.cdc.gov/flu/) |
| Varicella/Zoster | No |   |
| Hepatitis A | No |   |
| Conjugated Meningococcal (MCV4) | No |   |
| Human Papillomavirus (HPV) | No |   |

Note1: Based on input from the ACIP, professional societies, scientific leaders, and customers on October 26, 2009 Merck announced the company has decided not to resume production of ATTENUVAX® (Measles Virus Vaccine Live), MUMPSVAX® (Mumps Virus Vaccine Live), and MERUVAX®II (Rubella Virus Vaccine Live). This science-based decision will support vaccination of the largest group of appropriate individuals. Updated Jan 2010

Note2: Sanofi Pasteur is experiencing a manufacturing delay with Pentacel (DTaP-IPV/Hib) vaccine, which is anticipated to result in constrained supplies that will extend into the second half of 2016. However, Sanofi Pasteur has sufficient supplies of the relevant single antigen vaccines (DAPTACEL, ActHIB, and IPOL) to address the anticipated gap in Pentacel supply. Updated Jul 2016

FDA shortages

| **Generic Name or Active Ingredient** | **Status** |
| --- | --- |
| [Acetohydroxamic Acid (Lithostat) Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Acetohydroxamic%20Acid%20%28Lithostat%29%20Tablets&st=c&tab=tabs-1" \o "Link to Acetohydroxamic Acid (Lithostat) Tablets detail) | ***Currently in Shortage***  |
| [Ammonium Chloride Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Ammonium%20Chloride%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Anagrelide Hydrochloride Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Anagrelide%20Hydrochloride%20Capsules&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Aprepitant (Emend) Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Aprepitant%20%28Emend%29%20Capsules&st=r&tab=tabs-1) | ***Resolved***  |
| [Atropine Sulfate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Atropine%20Sulfate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Azathioprine Tablet](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Azathioprine%20Tablet&st=r&tab=tabs-1) | ***Resolved***  |
| [Bleomycin Sulfate for Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Bleomycin%20Sulfate%20for%20Injection&st=c&tab=tabs-1" \o "Link to Bleomycin Sulfate for Injection detail) | ***Currently in Shortage***  |
| [Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Caffeine%20Anhydrous%20%28125mg/mL%29;%20Sodium%20Benzoate%20%28125mg/mL%29%20Injection&st=c&tab=tabs-1" \o "Link to Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection detail) | ***Currently in Shortage***  |
| [Calcium Chloride Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Calcium%20Chloride%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Calcium Gluconate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Calcium%20Gluconate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Cefazolin Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cefazolin%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Cefepime Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cefepime%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Cefotaxime Sodium (Claforan) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cefotaxime%20Sodium%20%28Claforan%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Cefotetan Disodium Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cefotetan%20Disodium%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Ceftazidime and Avibactam (AVYCAZ) for Injection, 2.5g](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Ceftazidime%20and%20Avibactam%20%28AVYCAZ%29%20for%20Injection,%202.5g&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Chloramphenicol Sodium Succinate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Chloramphenicol%20Sodium%20Succinate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Chloroquine Phosphate Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Chloroquine%20Phosphate%20Tablets&st=r&tab=tabs-1) | ***Resolved***  |
| [Desmopressin Acetate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Desmopressin%20Acetate%20Injection&st=c&tab=tabs-1" \o "Link to Desmopressin Acetate Injection detail) | ***Currently in Shortage***  |
| [Dexamethasone Sodium Phosphate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dexamethasone%20Sodium%20Phosphate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Dextrose 5% Injection Bags](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dextrose%205per%20Injection%20Bags&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Dextrose Injection USP, 70%](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dextrose%20Injection%20USP,%2070per&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Dihydroergotamine Mesylate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dihydroergotamine%20Mesylate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Disopyramide Phosphate (Norpace) Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Disopyramide%20Phosphate%20%28Norpace%29%20Capsules&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Doxorubicin (Adriamycin) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Doxorubicin%20%28Adriamycin%29%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Doxorubicin Lyophilized Powder for Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Doxorubicin%20Lyophilized%20Powder%20for%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Epinephrine Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Epinephrine%20Injection&st=c&tab=tabs-1" \o "Link to Epinephrine Injection detail) | ***Currently in Shortage***  |
| [Eptifibatide (Integrilin) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Eptifibatide%20%28Integrilin%29%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Estradiol Valerate Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Estradiol%20Valerate%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Ethiodized Oil (Lipiodol) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Ethiodized%20Oil%20%28Lipiodol%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Fentanyl Citrate (Sublimaze) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Fentanyl%20Citrate%20%28Sublimaze%29%20Injection&st=c&tab=tabs-1" \o "Link to Fentanyl Citrate (Sublimaze) Injection detail) | ***Currently in Shortage***  |
| [Fomepizole Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Fomepizole%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Gemifloxacin Mesylate (Factive) Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Gemifloxacin%20Mesylate%20%28Factive%29%20Tablets&st=c&tab=tabs-1" \o "Link to Gemifloxacin Mesylate (Factive) Tablets detail) | ***Currently in Shortage***  |
| [Haloperidol Lactate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Haloperidol%20Lactate%20Injection&st=r&tab=tabs-1" \o "Link to Haloperidol Lactate Injection detail) | ***Resolved***  |
| [Imipenem and Cilastatin for Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Imipenem%20and%20Cilastatin%20for%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Indigotindisulfonate Sodium (Indigo Carmine) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Indigotindisulfonate%20Sodium%20%28Indigo%20Carmine%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Ketorolac Tromethamine Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Ketorolac%20Tromethamine%20Injection&st=r&tab=tabs-1" \o "Link to Ketorolac Tromethamine Injection detail) | ***Resolved***  |
| [L-Cysteine Hydrochloride Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=L-Cysteine%20Hydrochloride%20Injection&st=c&tab=tabs-1" \o "Link to L-Cysteine Hydrochloride Injection detail) | ***Currently in Shortage***  |
| [Leucovorin Calcium Lyophilized Powder for Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Leucovorin%20Calcium%20Lyophilized%20Powder%20for%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Leuprolide Acetate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Leuprolide%20Acetate%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Levetiracetam (Keppra) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Levetiracetam%20%28Keppra%29%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Lidocaine Hydrochloride (Xylocaine) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Lidocaine%20Hydrochloride%20%28Xylocaine%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [LifeCare PCA™ Sterile Empty Vial and Injector](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=LifeCare%20PCA%E2%84%A2%20Sterile%20Empty%20Vial%20and%20Injector&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Liotrix (Thyrolar) Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Liotrix%20%28Thyrolar%29%20Tablets&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Mecasermin [rDNA origin] (Increlex) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Mecasermin%20%5brDNA%20origin%5d%20%28Increlex%29%20Injection&st=c&tab=tabs-1" \o "Link to Mecasermin [rDNA origin] (Increlex) Injection detail) | ***Currently in Shortage***  |
| [Memantine Hydrochloride (Namenda) XR Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Memantine%20Hydrochloride%20%28Namenda%29%20XR%20Capsules&st=r&tab=tabs-1) | ***Resolved***  |
| [Meropenem for Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Meropenem%20for%20Injection,%20USP&st=r&tab=tabs-1) | ***Resolved***  |
| [Methyldopate Hydrochloride Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Methyldopate%20Hydrochloride%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Methylphenidate Hydrochloride ER Capsules/Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Methylphenidate%20Hydrochloride%20ER%20Capsules/Tablets&st=r&tab=tabs-1) | ***Resolved***  |
| [Methylprednisolone Sodium Succinate for Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Methylprednisolone%20Sodium%20Succinate%20for%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Metoprolol Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Metoprolol%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Morphine Sulfate Injection, USP, CII, (Preservative-Free)(For PCA Use Only)](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Morphine%20Sulfate%20Injection,%20USP,%20CII,%20%28Preservative-Free%29%28For%20PCA%20Use%20Only%29&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Multi-Vitamin Infusion (Adult and Pediatric)](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Multi-Vitamin%20Infusion%20%28Adult%20and%20Pediatric%29&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Mupirocin Calcium Nasal Ointment](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Mupirocin%20Calcium%20Nasal%20Ointment&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Nebivolol (BYSTOLIC) Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Nebivolol%20%28BYSTOLIC%29%20Tablets&st=r&tab=tabs-1" \o "Link to Nebivolol (BYSTOLIC) Tablets detail) | ***Resolved***  |
| [Nimodipine (Nymalize) Oral Solution](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Nimodipine%20%28Nymalize%29%20Oral%20Solution&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Penicillin G Benzathine (Bicillin L-A) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillin%20G%20Benzathine%20%28Bicillin%20L-A%29%20Injection&st=c&tab=tabs-1" \o "Link to Penicillin G Benzathine (Bicillin L-A) Injection detail) | ***Currently in Shortage***  |
| [Peritoneal Dialysis Solutions](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Peritoneal%20Dialysis%20Solutions&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Phentolamine Mesylate Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Phentolamine%20Mesylate%20Injection&st=r&tab=tabs-1) | ***Resolved***  |
| [Piperacillin and Tazobactam (Zosyn) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Piperacillin%20and%20Tazobactam%20%28Zosyn%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Potassium Acetate Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Potassium%20Acetate%20Injection,%20USP&st=r&tab=tabs-1) | ***Resolved***  |
| [Potassium Chloride Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Potassium%20Chloride%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Reserpine Tablets](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Reserpine%20Tablets&st=c&tab=tabs-1" \o "Link to Reserpine Tablets detail) | ***Currently in Shortage***  |
| [Sacrosidase (Sucraid) Oral Solution](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sacrosidase%20%28Sucraid%29%20Oral%20Solution&st=c&tab=tabs-1" \o "Link to Sacrosidase (Sucraid) Oral Solution detail) | ***Currently in Shortage***  |
| [Sodium Acetate Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Acetate%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Sodium Bicarbonate Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Bicarbonate%20Injection,%20USP&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Sodium Chloride 0.9% Injection Bags](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%200.9per%20Injection%20Bags&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Sodium Chloride 23.4% Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sodium%20Chloride%2023.4per%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Sufentanil Citrate (Sufenta) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sufentanil%20Citrate%20%28Sufenta%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Sumatriptan (Imitrex) Nasal Spray](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Sumatriptan%20%28Imitrex%29%20Nasal%20Spray&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Technetium Tc99m Succimer Injection (DMSA)](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Technetium%20Tc99m%20Succimer%20Injection%20%28DMSA%29&st=c&tab=tabs-1" \o "Link to Technetium Tc99m Succimer Injection (DMSA) detail) | ***Currently in Shortage***  |
| [Theophylline Extended Release Tablets and Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Theophylline%20Extended%20Release%20Tablets%20and%20Capsules&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Tigecycline (Tygacil) Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Tigecycline%20%28Tygacil%29%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Tiopronin (Thiola)](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Tiopronin%20%28Thiola%29&st=r&tab=tabs-1) | ***Resolved***  |
| [Tobramycin Injection](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Tobramycin%20Injection&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Tretinoin Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Tretinoin%20Capsules&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Triamcinolone Hexacetonide Injectable Suspension (Aristospan)](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Triamcinolone%20Hexacetonide%20Injectable%20Suspension%20%28Aristospan%29&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Trimipramine Maleate (SURMONTIL) Capsules](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Trimipramine%20Maleate%20%28SURMONTIL%29%20Capsules&st=c&tab=tabs-1) | ***Currently in Shortage***  |
| [Vancomycin Hydrochloride for Injection, USP](http://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vancomycin%20Hydrochloride%20for%20Injection,%20USP&st=c&tab=tabs-1" \o "Link to Vancomycin Hydrochloride for Injection, USP detail) | ***Currently in Shortage***  |

# DRUG

## FDA Approves New GLP-1 Receptor Agonist Adlyxin for Diabetes

<http://www.pharmacytimes.com/product-news/fda-approves-new-glp-1-receptor-agonist-adlyxin-for-diabetes?utm_source=Informz&utm_medium=Pharmacy+Times&utm_campaign=PT%5FBreaking%5FNews%5F7%2D28%2D16>

## FDA approves Lupin’s generic Klor-Con August 11, 2016

 <http://www.drugstorenews.com/article/fda-approves-lupins-generic-klor-con>

## Generic Dexedrine from Mylan Now Available

<http://www.pharmacytimes.com/product-news/generic-dexedrine-from-mylan-now-available?utm_source=Informz&utm_medium=Pharmacy+Times&utm_campaign=PT%5FeNews%5FDaily%5FUnsponsored%5F8%2D9%2D16>

# HOSPITAL

## CMS star ratings sneak peek shows rating system favors smaller hospitals with lower-risk patients

<http://www.fiercehealthcare.com/healthcare/cms-star-ratings-favor-smaller-hospitals-lower-risk-patients?utm_medium=nl&utm_source=internal&mrkid=799132&mkt_tok=eyJpIjoiTnpnM1lUUTBaV0pqTlROaiIsInQiOiI4S3lQVVVHKzc5RWxSNFhvUldCcnVCdEJHK0N4ZVBCTVwvXC90MnpyU3psaUNrTXFRa01QWWx0cDRtRFdxVGRBR3NQSjJkYTR2QTVkYW1qazlncU82M1plWEdYQTdwZFFoMkxnZzhONnMweFFZPSJ9>

## Micro-hospital' model could help underserved populations

<http://www.fiercehealthcare.com/healthcare/micro-hospital-model-could-help-underserved-populations?utm_medium=nl&utm_source=internal&mrkid=799132&mkt_tok=eyJpIjoiTnpnM1lUUTBaV0pqTlROaiIsInQiOiI4S3lQVVVHKzc5RWxSNFhvUldCcnVCdEJHK0N4ZVBCTVwvXC90MnpyU3psaUNrTXFRa01QWWx0cDRtRFdxVGRBR3NQSjJkYTR2QTVkYW1qazlncU82M1plWEdYQTdwZFFoMkxnZzhONnMweFFZPSJ9>

# FDA

## Latest Drug Safety Podcast



The FDA Drug Safety Podcasts are produced by FDA's Center for Drug Evaluation and Research (CDER). They provide emerging safety information about drugs in conjunction with the release of Public Health Advisories and other drug safety issues.

|  |  |  |  |
| --- | --- | --- | --- |
| FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects | July 26, 2016 | Listen to This Podcast*Run Time: 00:3:00* | [Transcript](http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm514482.htm) |
| FDA strengthens kidney warnings for diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR) | June 14, 2016 | Listen to This Podcast*Run Time: 00:3:04* | [Transcript](http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm507785.htm) |
| Update: FDA evaluating the risk of burns and scars with Zecuity (sumatriptan) migraine patch | June 10, 2016  |  Listen to This Podcast*Run Time: 00:1:12* |  [Transcript](http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm507770.htm) |
| FDA warns about serious heart problems with high doses of the antidiarrheal medicine loperamide (Imodium), including from abuse and misuse  | June 7, 2016 | Listen to This Podcast*Run Time: 00:3:00* | [Trans](http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm506835.htm) |

##

## **3 Federal Regulatory Changes Affecting Pharmacy**

<http://www.pharmacytimes.com/contributor/eric-roath-pharmd/2016/07/3-federal-regulatory-changes-affecting-pharmacy/P-1#sthash.dovkC2xj.dpuf>

<http://www.pharmacytimes.com/contributor/eric-roath-pharmd/2016/07/3-federal-regulatory-changes-affecting-pharmacy/P-3>

##

## Your Child's First Vaccines

<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/multi.html>

## Regulatory Reconnaissance

<http://www.raps.org/SearchRegFocus.aspx?tag=Regulatory%20Reconnaissance&utm_source=Email&utm_medium=Informz&utm_campaign=RF%2DToday>

## [FDA Announces Major Change in Pharmacy Inspections](#Submitted)

On July 12, FDA issued a [**notice**](http://echo4.bluehornet.com/ct/89637348%3ATl9j7aY5N%3Am%3A1%3A2753372985%3A9B164A1889AC403669A3F52CFFAF34C7%3Ar) announcing that it is changing its procedure for inspections of human drug compounders. Starting August 1, FDA inspectors will make a preliminary assessment of whether pharmacies are in compliance with 503A before applying 503B standards in “Form FDA-483” investigations and will not include observations in its Form-483 based “solely” on FDA’s good manufacturing practice (CGMP) requirements under 503B, unless it appears that pharmacies are compounding drugs that do not qualify for the 503A exemptions. However, FDA will still undertake inspections of 503A facilities, rather than complying with current statute and still intends to include CGMPs on Form FDA-483s, potentially for 503A pharmacies. APhA is working to clarify what factors FDA will use in the preliminary assessments; what standard FDA will use to determine “insanitary conditions”; what steps FDA will follow when it determines a pharmacy is a 503A; and to increase FDA’s communications on the status of inspections and enforcement actions with pharmacies and State Boards of Pharmacy.

## [APhA Responds to FDA Draft Compounding Guidances](#Inspections)

In April, FDA issued three draft guidance documents related to [**compounding**](http://echo4.bluehornet.com/ct/89637349%3ATl9j7aY5N%3Am%3A1%3A2753372985%3A9B164A1889AC403669A3F52CFFAF34C7%3Ar). After consulting with our Compounding Work Group and APhA membership, on July 18th, APhA commented on two of them (Prescription Requirement under 503A, Hospital and Health System Compounding). The first guidance would prohibit compounding for office use under 503A, further restrict the quantity that can be compounded in advance of a patient-specific prescription, overestimate the ability of 503B facilities to meet patient compounding needs, and attempt to define what constitutes a valid prescription. The second guidance would allow hospitals and health systems to distribute compounded drug products, without patient-specific prescriptions, for up to a 1-mile radius from their pharmacy within their own facilities. APhA urged FDA to return to its previous interpretation of 503A and allow pharmacists to continue compounding medications, without patient-specific prescriptions, for office use.

[Draft Guidance Documents Seek to Restrict Compounders from Making Copies of Commercially Available Drugs](#Compound)

On July 7, FDA issued two [draft guidance documents](http://echo4.bluehornet.com/ct/89637350%3ATl9j7aY5N%3Am%3A1%3A2753372985%3A9B164A1889AC403669A3F52CFFAF34C7%3Ar) (one for 503A and one for 503B facilities) describing how it will restrict the compounding of drugs that are essentially copies of commercially available or approved drugs. In the 503A draft guidance, FDA intends to consider a compounded drug product to be “essentially a copy of a commercially available drug,” if the compounded drug has the same active pharmaceutical ingredient(s) (API) as two or more commercially available drugs; API(s) have the same, similar, or an easily substitutable dosage strength and the commercially available drug can be administered used by the same route as prescribed for the compounded drug—unless a prescriber determines that there is a change made for an identified individual patient which produces a significant difference for that patient from the commercially available drug; and/or the drug cannot be compounded regularly (the drug is on a drug shortage list or the compounder fills four or fewer prescriptions for the relevant compounded drug in a calendar month). APhA is obtaining member feedback and plans on submitting comments.

# IMMUNIZATIONS

## Current Vaccine Shortages & Delays

<http://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html>

# INSURANCE

## Insurers restricting high-risk opioid users to select pharmacies

<http://drugtopics.modernmedicine.com/drug-topics/news/insurers-restricting-high-risk-opioid-users-select-pharmacies>

CMS Proposes Sweeping 'Episode Payment Models' for Cardiac Care, Hip/Femur Fracture Cases, Plus Changes to 'Comprehensive Care for Joint Replacement' Model

<http://www.jdsupra.com/legalnews/cms-proposes-sweeping-episode-payment-61655/>

## Medicare Advantage Value-Based Insurance Design Model

<https://innovation.cms.gov/initiatives/vbid/>

# NEWS

## Pedal Away From Type 2 Diabetes - Study finds biking may help adults avoid the blood sugar disorder

<https://medlineplus.gov/news/fullstory_159835.html>

Dietary Mineral Could Be One Key to Blood Pressure Control by: [Jonathan Goodman](http://www.cancertherapyadvisor.com/jonathan-goodman/author/3320/) - June 28, 2016

<https://medlineplus.gov/news/fullstory_159836.html>

## Survivors of Adult-onset Cancer Treated With Cisplatin Should Have Routine Auditory Exams

<http://www.cancertherapyadvisor.com/general-oncology/adult-onset-cancer-survivor-cisplatin-routine-auditory-exam-risk/article/506155/?DCMP=ILC-CTA_Promo_071116&cpn=&hmSubId=&hmEmail=zc9AEZF4x4rPbtLJAxJhmklDzcJVA8s10&NID=&dl=0&spMailingID=14938215&spUserID=NDgyNTEwMTE5NjYS1&spJobID=820818894&spReportId=ODIwODE4ODk0S0>

## Tools to make your headache visits more efficient

<http://www.medscape.com/infosite/197100.1/article-4?cp_available=true&src=1_invn_U_N>

* **SMP Medication Safety Alert! July 28, 2016 | Volume 21 | Issue 15**

[http://www.ismp.org/newsletters/acutecare/issues/20160728.pdf](http://www.mmsend42.com/link.cfm?r=b4zGaCUDR26Ivet0OUNsHQ~~&pe=oax_zy3jSBjKE52svVA4BkdiT15wHFSvSBAExoCzfOMHY9ioZ5DQopSqQzvw995fojKTB4SuDE02TugH2Nc0Ug~~)

## Could CoQ10 Benefit Heart Failure Patients?

<http://www.pharmacytimes.com/resource-centers/heart-failure/could-coq10-benefit-heart-failure-patients?utm_source=Informz&utm_medium=Pharmacy+Times&utm_campaign=PT%5FeNews%5FDaily%5FNCPA%5Fbarter%5F8%2D10%2D16>

## Retail 2027

<http://www.drugstorenews.com/retail-health-0?tp=i-H55-Q5U-1Or-1Z2hR-1v-wGU-1c-KVJ-1Z1Bk-sebVl&utm_campaign=RetailClinician&utm_source=Experian&utm_medium=email&cid=5385&mid=23128197>

## Obesity May Be Bad for the Brain, Too

<https://medlineplus.gov/news/fullstory_160349.html>

## Study: Meat and Sugar Contribute Equally to Obesity

<http://www.consultant360.com/exclusives/study-meat-and-sugar-contribute-equally-obesity>

## DASH Diet May Help To Prevent Gout Flares

<http://www.consultant360.com/exclusives/dash-diet-may-help-prevent-gout-flares>

## Could Eating More Nuts Reduce Inflammation?

<http://www.consultant360.com/exclusives/higher-consumption-nuts-may-reduce-inflammation>

## Heater-Cooler Devices

Heater-cooler devices are often necessary for use during surgeries to warm or cool patients

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm20082725.htm>

## Guest blog: More members of Congress pressure Medicare on DIR fees

<http://www.drugstorenews.com/article/guest-blog-more-members-congress-pressure-medicare-dir-fees?tp=i-H55-Q5U-1Pb-1aTi5-1v-wGU-1c-KgI-1aTQf-ZEMil&utm_campaign=Daily&utm_source=Experian&utm_medium=email&cid=5431&mid=23470353>

## Fake Xanax Cut With Potent Pain Med Can Be a Killer

* 1 person died, 8 were sickened when illicit pills circulated in San Francisco, doctors report
* <https://medlineplus.gov/news/fullstory_160329.html>