



Drug Recalls Alert

IEHP alerts the Physicians and Members when there is a Class I withdrawal or a voluntary Manufacturers' withdrawal notice via Letters. For Class II or voluntary recalls, they are routinely posted here as your reference. IEHP identifies and notifies Members and Prescribers within 30 calendar days of the Class II and voluntary recalls (when all lots are recalled).

Healthcare Providers should sign up to receive email notification from FDA regarding the latest Safety/Recall issues. <http://www.fda.gov/Safety/Recalls/default.htm>

2009

- [Mcneil Consumer Healthcare Announces A Voluntary Nationwide Recall Of All Lots Of Tylenol® Arthritis Pain 100 Count With Ez-Open Cap](#) (December 18, 2009)
- [Bayer Consumer Care Voluntarily Recalls One Lot of Combination Package of Alka-Seltzer Plus® Day & Night Cold Formula Liquid Gels](#) (December 08, 2009)
- [Hospira Issues Nationwide Voluntary Recall of Certain Lots of Liposyn™ and Propofol Products That May Contain Particulate Matter](#) (November 06, 2009)
- [Qualitest Pharmaceuticals Issues a Voluntary Nationwide Recall of All Accisure® Insulin Syringes](#) (October 27, 2009)
- [FDA Warns Consumers Not to Use Stolen Albuterol Sulfate Inhalation Solution and Ipratropium Bromide Inhalation Solution](#) (September 17, 2009)
- [Qualitest Pharmaceuticals, Inc. Issues a Voluntary Nationwide Recall of Accisure® Insulin Syringes \(1/2 Cc – 31 G – Short Needle\) Lot #6jcb1 and Accisure® Insulin Syringes \(1 Cc – 31 G – Short Needle\) Lot #7cpt1](#) (August 21, 2009)
- [Barr Laboratories, Inc. issues a voluntary nationwide recall of Dextroamphetamine/Amphetamine 20mg Tablets, Lot number 311756](#) (August 13)
- [Teva Pharmaceuticals USA issues a voluntary user-level nationwide recall of Propofol Injectable Emulsion 10 mg/mL 100 mL vials, lot numbers 31305429B and 31305430B](#) (July 16)
- [Brookstone Pharmaceuticals Issues a Voluntary Recall of All Lots of Brookstone Pharmaceuticals' Concentrated Acetaminophen Drops](#) (July 13)
- [Ther-Rx Corporation Issues Nationwide Voluntary Recall of Products](#) (January 28)
- [ETHEX Corporation Issues Nationwide Voluntary Recall of Products](#) (January 28)

2008

- [KV Pharmaceutical Voluntarily Suspends All Shipments of its Approved Tablet-form Drugs](#) (December 23)
- [ETHEX Corporation Initiated Nationwide Voluntary Recall of a Single Lot of Hydromorphone HCl 2 mg Tablets Due to Potential for Oversized Tablet](#) (December 23)
- [Drug Safety Information: Innohep \(tinzaparin sodium injection\)](#) (December 2)



- [Drug Safety Information: Phenytoin \(marketed as Dilantin, Phenytek and generics\) and Fosphenytoin Sodium \(marketed as Cerebyx and generics\) \(November 24\)](#)
- [Drug Safety Information: Bisphosphonates marketed as Alendronate \(Fosamax, Fosamax Plus D\), Etidronate \(Didronel\), Ibandronate \(Boniva\), Pamidronate \(Aredia\), Risedronate \(Actonel, Actonel W/Calcium\), Tiludronate \(Skelid\), Zoledronic acid \(Reclast, Zometa\) \(November 12\)](#)
- [Johnson and Johnson--Merck Consumer Pharmaceuticals Company Announces Urgent Voluntary Nationwide Recall Of Infants' Mylicon Gas Relief Dye Free Drops \(Simethicone-Antigas\) Non-Staining Due To Possible Metal Fragments \(November 7\)](#)
- [ETHEX Corporation Initiated Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets \(November 7, 2008\)](#)
- [FDA Reports Nationwide Recall of Mislabeled ReliOn Insulin Syringes \(November 5, 2008\)](#)
- [ETHEX Corporation Voluntarily Recalls Three Lots of Dextroamphetamine Sulfate 5mg Tablets Due to the Potential for Oversized Tablets \(October 15, 2008\)](#)
- [Actavis Totowa Announces Voluntary Recall at the Retail Level of All Drug Products Manufactured at its Little Falls, New Jersey Facility \(August 1, 2008\)](#)
- [Roxane Laboratories, Inc. Initiates a Nationwide Voluntary Recall of Two Manufacturing Lots of Sodium Polystyrene Sulfonate Suspension in the US and Puerto Rico \(July 14\) \(July 14\)](#)
- [ETHEX Corporation Voluntarily Recalls Specific Lots of 30 mg. and 60 mg. Morphine Sulfate Extended Release Tablets Due to the Potential for Oversized Tablets NDC #58177-320-04 & 58177-330-04 \(June 13\)](#)
- [ETHEX Corporation Voluntarily Recalls a Single Lot of Morphine Sulfate 60 mg Extended Release Tablets Due to the Potential for Oversized Tablets \(June 9\)](#)
- [FDA Requests Recall of Xiadafil VIP Tabs \(May 27\)](#)
- [Actavis Totowa \(formerly known as Amide Pharmaceutical, Inc.\) recalls all lots of Bertek and UDL Laboratories Digitek® \(digoxin tablets, USP\) as precaution \(April 25\)](#)
- [Covidien Initiates Voluntary Recall of Pre-Filled Syringes Containing Heparin \(March 28\)](#)
- [B. Braun's Supplier Recall of Heparin API Prompts Voluntary Recall of Heparin Solutions \(March 21\)](#)
- [American Health Packaging Announces a Recall of Approximately 1,400 Units of Heparin Sodium Vial Products as Part of Broader Baxter Recall \(March 20\)](#)
- [Baxter to Proceed with Recall of Remaining Heparin Sodium Vial Products \(Feb. 28\)](#)
- [PRICARA™ RECALLS 25 mcg/hr DURAGESIC® \(fentanyl transdermal system\) CII PAIN PATCHES \(Feb. 12\)](#)
- [Baxter Issues Urgent Nationwide Voluntary Recall of Heparin 1,000 Units/ml 10 and 30ml Multi-Dose Vials \(Jan. 25\)](#)

2007

- [AM2 PAT, Inc. Issues Nationwide Recall of Pre-Filled Heparin Lock Flush Solution USP \(5 mL in 12 mL Syringes\) \(December 20, 2007\)](#)

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- [Recall: Bayer Ascensia Contour Blood Glucose Monitoring System](#) (*July 13, 2007*)

Background and Recalls

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- **Market withdrawal:** occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.
- **Medical device safety alert:** issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls.