

GlucaGen HypoKit (glucagon [rDNA origin] for injection).

On 09/08/2016, Novo Nordisk recalled (FS6X270, FS6X296, FS6X538, FS6X597, FS6X797, FS6X875) of GlucaGen HypoKit (glucagon [rDNA origin] for injection) (NDC# 0169-7065-15) Defective delivery system: detached needles on the syringe in the kit.

The U.S. Food and Drug Administration (FDA) has issued a Class I of the affected medications. More information about the recall is at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

<p>Recalled Drug: GlucaGen HypoKit (glucagon [rDNA origin] for injection). NDC Number: 0169-7065-15 Lot Numbers: FS6X270, FS6X296, FS6X538, FS6X597, FS6X797, FS6X875 Expiration Date: 9/30/2017</p>
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What you should do:

- **Do not continue to use GlucaGen HypoKit (glucagon [rDNA origin] for injection) if it has been recalled.**
- Check your prescription label to see if you have GlucaGen HypoKit (glucagon [rDNA origin] for injection).
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Senna Syrup (sennosides) 8.8 mg, 8 fl. oz. (237 mL) bottle

On 8/8/2016, Major Pharmaceuticals recalled Senna Syrup (sennosides) Syrup (NDC# 0904-6289-09). This recall was initiated as a precautionary measure due to a potential risk of product contamination with the bacteria *B. cepacia*.

The U.S. Food and Drug Administration (FDA) has issued a Class II of the affected medications. More information about the recall is at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

<p>Recalled Drug: Senna Syrup (sennosides) 8.8 mg NDC Number: 0904-6289-09 Lot Number: 20391517, 20391518, 20391519, 20391601, 20391602, 20391604, 20391605, 20391608. Expiration Date: 09/17, 10/17, 11/17, 01/18, 02/18, 03/18, 06/18.</p>
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What you should do:

- **Do not continue to use Senna Syrup (sennosides) if it has been recalled**
- Check your prescription label to see if you have Senna Syrup (sennosides).
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Senexon Liquid (sennosides) 8.8 mg, 8 fl oz. (237 mL)

On 8/8/2016, Rugby Laboratories recalled Senexon Liquid (sennosides) (NDC# 0536-1000-59). This recall was initiated as a precautionary measure due to a potential risk of product contamination with the bacteria *B. cepacia*.

The U.S. Food and Drug Administration (FDA) has issued a Class II of the affected medications. More information

about the recall is at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

Recalled Drug: Senexon Liquid (sennosides) 8.8 mg

NDC Number: 0536-1000-59

Lot Number: 20391515, 20391516, 20391517, 20391518, 20391520, 20391521, 20391601, 20391603, 20391604, 20391606, 20391607, 20391609.

Expiration Date: 08/17, 09/17, 10/17, 11/17, 12/17, 01/18, 03/18, 04/18, 06/18.

What you should do:

- **Do not continue to use Senexon Liquid (sennosides) 8.8 mg if it has been recalled**
- Check your prescription label to see if you have < Senexon Liquid (sennosides) 8.8 mg.
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Diecto Syrup (docusate sodium), 60 mg/15 mL

On 8/8/2016, Rugby Laboratories recalled Diecto Syrup (docusate sodium), 60 mg/15 mL (NDC# 0536-1001-85). This recall was initiated as a precautionary measure due to a potential risk of product contamination with the bacteria *B. cepacia*. The U.S. Food and Drug Administration (FDA) has issued a Class II of the affected medications. More information about the recall is at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

Recalled Drug: Diecto Syrup (docusate sodium), 60 mg/15 mL NDC Number: 0536-1001-85
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What you should do:

- **Do not continue to use Diecto Syrup (docusate sodium), 60 mg/15 mL if it has been recalled**
- Check your prescription label to see if you have Diecto Syrup (docusate sodium), 60 mg/15 mL.
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Sennazon (sennosides) Syrup, 8.8 mg, 8 fl. oz. (237 mL) bottle

On 8/8/2016, Bayshore Pharmaceuticals recalled Sennazon (sennosides) Syrup (NDC# 76518-100-08). This recall was initiated as a precautionary measure due to a potential risk of product contamination with the bacteria *B. cepacia*. The U.S. Food and Drug Administration (FDA) has issued a Class II of the affected medications. More information about the recall is at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

Recalled Drug: Sennazon (sennosides) Syrup NDC Number: 76518-100-08
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What you should do:

- **Do not continue to use Sennazon (sennosides) Syrup if it has been recalled**
- Check your prescription label to see if you have Sennazon (sennosides) Syrup.
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Albuterol Sulfate Syrup, 2 mg/ 5 mL, 473 mL bottle

On 06/22/2016, Teva Pharmaceuticals recalled Lot # 95113 of Albuterol Sulfate Syrup, 2 mg/ 5 mL, 473 mL bottle (NDC# 0093-0661-16) due to the presence of foreign substances; presence of black particles described generically as cellulose-based bundles of brown fibrous material. The U.S. Food and Drug Administration (FDA) has issued a Recall Class II of the affected medications. More information about the recall can be found at: <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>.

The detailed information of the recalled product is listed below:

<p>Recalled Drug: Albuterol Sulfate Syrup, 2 mg/ 5 mL NDC Number: 0093-0661-16 Lot Numbers: 95113 Expiration Date: 01/2017</p>
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What you should do:

- **Do not continue to use Albuterol Sulfate Syrup, 2 mg/ 5 mL if it has been recalled**
- Check your prescription label to see if you have Albuterol Sulfate Syrup, 2 mg/ 5 mL.
- If you have the medication, contact the pharmacy that you received it from.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

Cubicin® (daptomycin) for Injection

Cubist Pharmaceuticals has announced the recall of multiple lots of Cubicin® (daptomycin) for injection because vials may contain glass particles. The affected vials are 500mg in 10 mL single-dose (NDC 67919-0011-01).

A complete list of recalled lots and expiration dates is at:

<http://www.cubist.com/downloads/c-al-080614.pdf>.

More information about the recall is at:

<http://www.fda.gov/Safety/Recalls/ucm408576.htm>.

Cubist Pharmaceuticals recommends that:

- Recalled product should be quarantined.
- Customers who have recalled product should contact Cubist at 1-855-534-8309 Monday through Friday from 9:00 a.m. to 7:00 p.m. ET to arrange for instructions on how to return recalled product.
- For medical questions, contact Cubist Medical Information should be contacted at: 1-877-282-4786 between 8:00 a.m. and 5:30 p.m. ET, Monday through Friday.

- Adverse events from the use of prescription drugs should be reported to FDA by calling 1-800-332-0178 or visiting www.fda.gov/medwatch/report.htm.

Advocate Redi-Code Plus Blood Glucose Test Strips

On June 6, 2014, Diabetic Supply of Suncoast, Inc. recalled all lots of Advocate Redi-Code Plus Blood Glucose Test Strips (NDC – 94046-0001-57). Package labels for the recalled strips do not include the model number (BMB-BA006A). The strips were manufactured by BroadMaster Bio-Tech Corp. for specific blood glucose meters also made by BroadMaster. If the strips are used with similar meters from a different company, blood glucose readings may be inaccurate, potentially leading to serious adverse effects.

Specifics of the recall:

Product Description	NDC Number	Lot Number	Expiration Date	Manufacturer
Advocate Redi-Code Plus Blood Glucose Test Strips	94046-0001-57	All	All	Diabetic Supply of Suncoast, Inc.

Diabetic Supply of Suncoast, Inc. recommends that:

- Recalled strips should not be used.
- Customers who have recalled strips should contact the company at 561-296-0488 between the hours of 9:00am and 5:00pm ET, Monday through Friday for instructions on how to have recalled product replaced.
- Patients or caregivers of patients who received recalled strips should talk with their prescribers.
- More information about the Advocate Redi-Code Plus Blood Glucose Test Strips recall is at: <http://www.fda.gov/Safety/Recalls/ucm400559.htm>
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

[1% Lidocaine injection 10 mg/mL, 30 mL preservative free single use vial 10% from Hospira Inc. and Cubicin \(Daptomycin for injection\) 500 mg/10 mL vials from Cubist Pharmaceutical](#)

On April 18, 2014, two products were recalled by their respective manufacturers. There was no impact on members of Community Health Plan of Washington. The recall products are listed below:

Product description	NDC number	Lot Number	Expiration Date	Manufacturer
1% Lidocaine injection (10mg/mL) 30mL preservative free single use vials	0409-4279-02	31-427-DK	July 1, 2015	Hospira Inc
Cubicin (Daptomycin for injection)500mg/10ml vials	67919-0011-01	280453F	April 2016	Cubist Pharmaceutical

The manufacturers recommend that:

- Patients, caregivers and providers should check supplies of Lidocaine for the recalled lot number. Product from the affected lot should not be used.
- For medical questions about the recall of Lidocaine injection vials, contact Hospira Medical Communications at 1-800-615-0187.
- To arrange for return of recalled Lidocaine product, contact Stericycle at 1-888-835-2723 between the hours of 8 a.m. and 5 p.m. ET, Monday through Friday.
- For questions regarding Cubicin injection, contact Cubist Medical Information at 1.877.282.4786 between the hours of 8 a.m. to 5:30 p.m. EST, Monday through Friday.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

[Propofol injectable emulsion from Hospira Inc.](#)

On April 2, 2014, Hospira recalled seven lots of Propofol injectable emulsion because glass defects and floating metal particles were observed in reserve vials. Particles in the medication may interfere with administration; particles that enter the patient's blood may cause inflammation, capillary occlusion or immune response that could eventually lead to granuloma formation.

The detailed information of the recalled product is listed below:

Product description	NDC number	Lot Number	Expiration Date	Manufacturer
Propofol Injectable	0409-4699-30	29-614-DJ, 29-615-DJ, 29-616-DJ, 29-617-DJ,	May 1, 2015	Hospira Inc

Emulsion		29-628-DJ, 29-629-DJ, 29-630-DJ		
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Our records showed no current utilization of these products by members of CHPW.

The manufacturers recommend that:

- Patients, caregivers and providers should check supplies of Propofol for the recalled lot number. Product from the affected lot should not be used.
- For medical questions about the recall, contact Hospira Medical Communications at 1-800-615-0187
- To arrange for return of recalled product, contact Stericycle at 1-877-272-2158 between the hours of 8 a.m. and 5 p.m. ET, Monday through Friday.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

[Effexor XR 150mg and one lot of Greenstone Venlafaxine 150mg extended-release capsules](#)

On March 6, 2014 Pfizer recalled two lots of **Effexor XR 150mg** and one lot of **Greenstone Venlafaxine 150mg extended-release capsules**.

The recalled drugs and lot numbers are listed below:

Drug name	Lot number (NDC number)	Manufacturer	Expiration Date
Effexor XR 150mg capsules	V130142 (NDC 0008-0836-21)	Pfizer	October 2015
Effexor XR 150mg capsules	V130140 (NDC 0008-0836-22)	Pfizer	October 2015
Venlafaxine 150mg extended release capsules	V130014 (NDC 59762-0182-02)	Greenstone	August 2015

One bottle of Effexor XR contained a capsule of Tikosyn® (dofetilide), an antiarrhythmic used to convert and maintain normal sinus rhythm for patients with atrial fibrillation and atrial flutter. Taking Tikosyn instead of the antidepressant, venlafaxine, could result in heart rhythm changes that could be serious or possibly life-threatening.

Pfizer recommends that:

- Pharmacists quarantine recalled lots, notify patients who received affected product and arrange returns with Stericycle at 1-888-345-0481 Monday to Friday 8am to 5pm ET.
- Patients with prescriptions from affected lots notify their physicians and return prescriptions to the pharmacies that filled them.
- Questions about the recall may be directed to Pfizer Medical Information at 1-800-438-1985 Monday to Thursday 9am to 8pm ET, Friday 9am to 5pm ET.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch/report.htm or calling 1-800-FDA-0178.

More information about the recall is at:

<http://www.fda.gov/Safety/Recalls/ucm388329.htm>.

[Acetylcysteine 10% Solution Lot Number 2005479 from Roxane](#)

On February 14, 2014 Ben Venue Laboratories recalled one lot of acetylcysteine solution 10% that is manufactured for Roxane Laboratories. One vial from the affected lot was observed to contain a glass particle. Inhaled or swallowed glass particles can cause choking or interfere with breathing. Particles lodged in the throat or airways may cause bleeding, irritation and infection. Any of the adverse effects have potential to be life-threatening.

Specifics of the recall lot:

Name: acetylcysteine solution 10%, from Roxane

NDC number 0054-3025-02

Lot number: 2005479

Expiration Date: March 2014

Ben Venue recommends the following:

- Patients and providers should check supplies of **acetylcysteine solution 10%** from **Roxane**. Product from the recalled lot should not be used.
- For returns, contact the distributor, GENCO Pharmaceutical Services at 1.800.633.1422.
- For questions about the recall, contact Roxane Technical Product Information at 1.800.962.8364 or <https://www.roxane.com/contact.html>.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

As of February 28, 2014, no utilization of this product was identified among members of Community Health Plan of Washington

Abbott Recalls FreeStyle and FreeStyle Lite Blood Glucose Test strips

Abbott announced a voluntary recall of 20 lots of FreeStyle and FreeStyle Lite Blood Glucose Test Strips. This recall is being conducted because the affected test strips will produce out of range control solution results and low blood glucose readings when used with older technology blood glucose meters such as FreeStyle Flash and FreeStyle Blood Glucose meters build into the OmniPod system.

The affected FreeStyle and FreeStyle Lite Blood Glucose test strip lot numbers are :

1281732, 1283345, 1283603, 1285007, 1350414, 1363015, 1363109, 1363321, 1365056, 1365920, 1365921, 1365934, 1366006, 1366111, 1366337, 1366347, 1366515, 1367917, 1373262, 1374907.

Blood glucose test results are not affected when these test strips are used with the newer FreeStyle brand meters such as FreeStyle Freedom, FreeStyle Lite, FreeStyle Freedom Lite and FreeStyle Insulinx Blood Glucose meters.

Abbott is notifying patients of this recall directly, and a notification letter has been posted to the Abbot Diabetes Care website, www.AbbottDiabetesCare.com.

Patients who are currently using FreeStyle or FreeStyle Lite test strips of the affected lots, please contact Abbot Diabetes Care Customer Service immediately at 1-888-736-9869 for a no-charge replacement of the test strips.

Patients not using test strips from the affected lots can continue to use the strips.

Recall: Warfarin 2 mg Tablets by Zydus Pharmaceuticals USA Inc – Due to Oversized Tablets

Zydus Pharmaceuticals USA Inc. is involuntarily recalling one lot of warfarin 2 mg tablets, Lot #MM5767, expiration date June 2014 to the retail level. Four tablets of warfarin 2 mg tablets, Lot MM5767, have been found to be oversized in one product complaint.

Ingestion of a greater than intended dose of warfarin, could lead to an increased pharmacological effect of warfarin. As a result, patients would be more likely to develop bleeding as an adverse reaction and in some patients that bleeding into a critical organ (mostly the central nervous system) could be fatal. The risk of bleeding is increased if overdosing is repeated continuously on a daily basis.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this particular lot of warfarin 2 mg tablets. In case consumers have tablets of this lot of product, make sure all the tablets are of same size and if unsure, consumers should consult their dispensing pharmacy.

For complete MedWatch Safety Alert including link to Firm Press Release:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm356519.htm>

[Estarylla \(norgestimate and ethinyl estradiol\): Recall – Report of Placebo Tablet Present in a row of Active Tablets](#)

Sandoz notified the public it is conducting a voluntary nationwide recall to the retailer level of one lot of its Estarylla (norgestimate and ethinyl estradiol) tablets in the U.S., following a customer report of a placebo tablet present in a row of active tablets on one pack.

The lot number, expiration date, and NDC code of the recalled lot is: LF01213A, expiration date 02/2014, NDC 00781-4058-15. It is supplied in cartons containing 3 blister cards of 28 tablets each.

The Sandoz Drug Information Direct Line is open at 800-525-2492, 24 hours/day, 7 days a week.

For more details, please visit at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359656.htm?source=govdelivery>

[Class I Recall: LifeScan, Inc. One Touch Verio IQ Blood Glucose Meter– Failure to Provide a Warning at Extremely High Blood Glucose Levels](#)

At extremely high blood glucose levels of 1024 mg/dL and above, the OneTouch Verio IQ Meter will turn off instead of displaying the message “EXTREME HIGH GLUCOSE above 600 mg/dL” as intended. When turned back on, the meter enters the set-up mode and requires the user to confirm the date and time settings before being able to test again. However, if the glucose level is still measuring 1024 mg/dL or above when testing, the meter will shut down again.

All OneTouch Verio IQ Blood Glucose Meters are being recalled and were distributed from December 14, 2011 through March 7, 2013.

If the One Touch Verio IQ Meter unexpectedly turns off and enters set-up mode after turning

it back on, blood glucose may be extremely high, and you should call your health care professional. Call LifeScan Customer Service at 1-800-717-0276 for support.

[Abbott Recalls FreeStyle Insulin Blood Glucose Meters](#)

Abbott announced a voluntary recall and software update or replacement of all FreeStyle Insulin Blood Glucose Meters. This recall is being conducted because the blood glucose machine will display very high blood glucose level of 1024 mg/dL and above and store in memory an incorrect test result that is 1024 mg/dL below the measured result. According to Abbott, the likelihood of experiencing extremely high blood glucose levels of 1024 mg/dL and above is unlikely. However, when they occur, they are a serious health risk and require immediate medical attention.

Abbott is notifying patients of this recall directly. Patients can continue to test with their meter while they are waiting for their replacement meter to arrive as long as they are aware of this issue. Patients can access a software update to resolve the issue at <http://www.freestyleinsulin.com/swupdate>. Patients can also contact Abbott Diabetes Care Customer Service at 1-866-723-2697 to arrange to receive a replacement meter at no charge. More information can be found on the Abbott's website at: <https://www.abbottdiabetescare.com/press-room/2013/2013-c.html>

[Advanced Pharmaceutical Inc. Recall of Ferrous Sulfate 325 mg Tablets Labeled as Rugby Natural Iron Supplement – Bottle may Contain Meclizine HCl 25 mg Tablets](#)

Advance Pharmaceutical Inc. notified the public of a recall of one lot of Ferrous Sulfate tablets 325 mg, after notification by a pharmacist that a bottle of Ferrous Sulfate tablets 325 mg contained Meclizine HCl 25 mg tablets. The lot of the Rugby Ferrous Sulfate is 12G468. Expiration date for the lot is July 2014.

Taking Meclizine HCl 25 mg as Ferrous Sulfate 325 mg may cause serious side effects to those who consume sedatives or alcohol, those with a pre-existing CNS disorder, those with impaired kidney or liver function, the elderly, nursing infants of lactating mothers who received the drug and newborns of mothers who received the drug immediately before childbirth.

Consumers who have the affected lot should not take the product. They may contact Advance Pharmaceutical with questions at 631-981-4600, ext 300, Monday through Friday between 8:30 a.m. and 4:30 p.m. ET.

For more detail information, please read the MedWatch safety alert

at:<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm336137.htm>

[Mylan Hydrocodone Bitartrate and Acetaminophen Tablets 10 mg/500 mg– Potential for Oversized Tablets](#)

December 21, 2012– Mylan announced a voluntary nationwide recall to the retail level of 3 lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg (Lot numbers are 3037841, 3040859, and 3042573). The three affected lots, manufactured by Qualitest Pharmaceuticals, were repackaged and distributed by Mylan in unit dose (CD 100) under the UDL Laboratories label.

The affected lots may contain tablets that have a higher dosage of acetaminophen, and as a result, it is possible that consumers could take more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day.

The affected lots of Hydrocodone Bitartrate and Acetaminophen tablets, USP 10 mg/500 mg were distributed between February 20, 2012 and November 19, 2012 to wholesale distributors and retail pharmacies nationwide.

Consumers who have the affected lots should contact Qualitest at 1-800-444-4011. Consumers who are not sure if they have the affected lot number should consult their pharmacy or health care professional.

For more information, please

visit:<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm331224.htm>

[Ranbaxy Pharmaceuticals Inc. Retail-Level Recall of Generic Atorvastatin](#)

November 26, 2012– Ranbaxy has announced a retail or pharmacy level recall of multiple lots of atorvastatin, a generic version of Liptior. This voluntary recall is being issued because of a potential for these batches to contain small glass particles less than one millimeter in size. The recall includes several lots of Ranbaxy's atorvastatin 10 mg, 20 mg, and 40 mg tablets that were distributed between September 25, 2012 and October 26, 2012. It does not include the 80 mg tablets.

The affected lot numbers can be found at: <http://www.ranbaxy.com/Atorvastatin.aspx>

Consumers who have the affected product should return the product to the pharmacy. For more detailed information, please visit Ranbaxy Pharmaceutical Inc.

at: <http://www.ranbaxy.com/> under Atorvastatin recall.

[Watson Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg/500mg Due to the Potential for Oversized and Superpotent Tablets](#)

September 20, 2012– Watson Laboratories, Inc. today issued a voluntary nationwide recall for two lots of Hydrocodone Bitartrate and APAP Tablets, USP 10 mg/500 mg. A customer complaint was received for tablets that were thicker and darker shade than the other tablets. It is possible that some tablets from lots 519406A and 521759A exceed the weight specification and may contain higher than indicated amounts of the ingredients Hydrocodone Bitartrate and/or Acetaminophen. Unintentional ingestion of excessive amounts of acetaminophen may potentially result in an adverse event, including liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death. Unintentional ingestion of excessive amounts of hydrocodone may result in an adverse event, including an increase in the severity or frequency of side effects, such as sedation or respiratory depression, particularly in patients who are elderly, have severe kidney or liver impairment, or are also taking interacting medications, for example other sedating medications or certain antidepressants.

The affected lot of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg, 500 count NDC 00591-0540-05, Lot Numbers 519406A and 521759A both with the expiry date April 2014 were distributed between June 27 and July 18, 2012 to wholesale distributors and retail pharmacies nationwide. The lot numbers can be found on the manufacturer's bottle label. Hydrocodone Bitartrate and Acetaminophen Tablets are approximately 0.6 inches in length, blue, bisected capsule shaped, with "Watson 540" de-bossed on one side of the tablet.

Consumers who have lots 519406A or 521759A should contact their pharmacy or health care professional. Consumers who are unsure if they have the affected lot numbers should consult their pharmacy or health care professional.

For more information please visit: <http://www.fda.gov/Safety/Recalls/ucm320566.htm>

Qualitest Hydrocodone Bitartrate and Acetaminophen Tablets 10mg/500mg – Potential for Oversized Tablets

September 10, 2012– Qualitest issued a voluntary, nationwide retail level recall for one lot of Hydrocodone Bitartrate and Acetaminophen tablets, USP 10mg/500mg. Bottles from the affected lot may contain tablets that have a higher dosage of acetaminophen, and as a result, it is possible that consumers could take more than the intended acetaminophen dosage. Unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day.

The affected lot of Hydrocodone Bitartrate and Acetaminophen tablets, USP 10mg/500mg, C1440512A, was distributed between May 14 and August 3, 2012 to wholesale distributors and retail pharmacies nationwide. The lot number can be found on the side of the manufacturer's bottle.

Consumers who have lot C1440512A should contact Qualitest at 1-800-444-4011. Consumers who are not sure if they have the affected lot number should consult their pharmacy or health care professional.

For more information, please visit: <http://www.fda.gov/Safety/Recalls/ucm318827.htm>

Voluntary Recall of One Lot of Nimodipine Capsules due to Crystallization of the Fill Material

On September 4, 2012, Sun Pharmaceutical Industries, Inc (Sun Inc) announced that it is voluntarily recalling from users one lot of Nimodipine capsules, 30 mg, marketed by Caraco Pharmaceutical Laboratories, Ltd. Sun Inc. commenced the recall as a precautionary measure due to the presence of crystals of nimodipine within the capsule solution of this lot as identified by a customer complaint. No adverse events have been reported at this time.

The affected product was distributed nationwide between January 19, 2012 and April 24 2012. The crystallization of the nimodipine fill material in the capsule could adversely affect the product's bioavailability. Although clinical health implications are unknown, use of the product when the nimodipine has crystallized in the capsule may be of great clinical significance. The product may no longer be bioequivalent and may potentially affect patients who are being treated for a medical emergency.

As a precautionary measure, Sun Inc is recalling the following lot numbers to the consumer level to minimize any potential risk to patients:

Lot Number	NDC Number
3305.039A	57664-135-65
3305.039B	57664-135-64

The recalled capsules were manufactured for Sun Inc by Pharmaceuticals International, Inc. This recall is being conducted with the knowledge of the Food and Drug Administration.

Patients and healthcare providers using Nimodipine Capsules, 30 mg, with one of the above lot numbers should discontinue use of the product and should contact the following number for more information about the recall on Monday through Friday from 8 a.m. to 5 p.m. EST: Inmar Inc. at 1-800-967-5952 (Option 1, then Option 3).

[Norgestimate and Ethinyl Estradiol Tablets Recall – Packaging Error, Potential for Incorrect Dosing Regimen](#)

Glenmark Generics Inc. issued a nationwide, consumer-level recall of 7 lots of Norgestimate and Ethinyl Estradiol tablets USP (0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg) because of a packaging error: Select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect. This could leave women without adequate contraception and at risk for unintended pregnancy.

Consumers exposed to affected packaging should begin using a nonhormonal form of contraception immediately. Patients who have the affected product should notify their physician and return the product to the pharmacy.

Lot numbers are as follows for affected packs of Norgestimate and Ethinyl Estradiol tablets USP, 0.18 mg/0.035mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (generics):

NDC	LOT #	EXP. DATE
68462-565-29	04110101	07/31/2013
68462-565-29	04110106	07/31/2013
68462-565-29	04110107	07/31/2013
68462-565-29	04110114	08/31/2013

NDC	LOT #	EXP. DATE
68462-565-29	04110124	08/31/2013
68462-565-29	04110129	08/31/2013
68462-565-29	04110134	09/30/2013

For more information about this recall, please visit [the FDA website](#).

[Lo/Ovral®-28 \(Norgestrel/Ethinyl Estradiol\) Tablets Recall — Possibility of Inexact Tablet Counts or Out of Sequence Tablets](#)

Pfizer Inc. notified health care professionals and consumers that it voluntarily recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) Tablets and 14 lots of Norgestrel and Ethinyl Estradiol Tablets (generic) for customers in the U.S. market. An investigation by Pfizer found that some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy.

Patients who have the affected product should notify their physician and return the product to the pharmacy. See Table 1 for a list of affected lot numbers.

Table 1. Lot numbers of affected packs of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) Tablets and Norgestrel and Ethinyl Estradiol Tablets (generic)

NDC	Product Name	Lot #	Expiration Date	Configuration/ Count
24090-801-844	LO/OVRAL® 28	E15678	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E15679	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E15686	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E15687	01/31/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E15690	01/31/2014	6 Pilpacks® of 28 tablets each

NDC	Product Name	Lot #	Expiration Date	Configuration/ Count
24090-801-844	LO/OVRAL® 28	E15698	01/31/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E15700	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E80434	07/31/2013	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	E80438	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	F36908	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	F36909	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	F43915	03/31/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	F43926	03/31/2014	6 Pilpacks® of 28 tablets each
24090-801-844	LO/OVRAL® 28	F43927	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	E15677	08/31/2013	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	E15704	01/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	E15706	01/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	E80440	08/31/2013	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/	F16388	01/31/2014	6 Pilpacks® of

NDC	Product Name	Lot #	Expiration Date	Configuration/ Count
	Ethinyl Estradiol 0.03 mg			28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F16390	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F22132	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F31330	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F36911	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F36913	03/31/2014e	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F43924	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F43925	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F43934	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84c	Norgestrel 0.3 mg/ Ethinyl Estradiol 0.03 mg	F53238	03/31/2014	6 Pilpacks®

Patients who have the affected product should notify their physician and return the product to the pharmacy.

For more detailed information, please read the [FDA MedWatch safety alert](#).

Qualitest Pharmaceuticals Issues a Nationwide Voluntary Recall of Oral Contraceptives

Qualitest Pharmaceuticals issued a voluntary recall of multiple lots of oral contraceptives. The recall is being implemented because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible. This packaging error and the potential for this error to have affected other oral contraceptive products resulted in the company issuing the recall of multiple lots.

As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. These packaging defects do not pose any immediate health risks. However, consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately and consult their health care provider or pharmacist.

The recall is effective immediately and includes the following products:

- Cyclofem™ 7/7/7
- Cyclofem™ 1/35
- Emoquette™
- Gildess® FE 1.5/30
- Gildess® FE 1/20
- Orsythia™
- Previfem®
- Tri-Previfem®

The affected lot numbers can be found at the following URL:

<http://www.qualitestrx.com/pdf/OCRecall.pdf>.

Doctors, pharmacists or women seeking additional information on this recall, or consumers who have affected products, should contact Qualitest at 1-877-300-6153, 8:00 a.m. to 5:00 p.m. CT Monday through Friday for information or to arrange return of any affected product. The lot numbers can be found on the bottom of the box or the individual blister card.

Adverse reactions or quality problems experienced with the use of these products may be reported to Qualitest at 1-877-300-6153 or to the FDA's MedWatch Adverse Event Reporting program either online (www.fda.gov/medwatch/report.htm), by regular mail (mail to address on the pre-addressed form) or by fax (1-800-FDA-0178).

[Endo Pharmaceuticals Issues Voluntary Recall of Two Lots of Endocet® \(oxycodone/acetaminophen 10/325 mg\)](#)

Endo Pharmaceuticals issued a voluntary recall of Endocet® (oxycodone/acetaminophen 10/325 mg, NDC 60951-712-70, lot # 402415NV and # 402426NV). One bottle from each lot of Endocet® 10/325 mg was found to contain some Endocet® 10 mg/650 mg tablets, which are identifiable by their larger size, and different shape and markings. Currently, no other bottles from the subject lots or any other lots have been found to erroneously contain Endocet® 10 mg/650 mg tablets.

Due to the recalled bottles containing incorrect tablets that have a higher dosage of acetaminophen, consumers may take more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content may result in liver toxicity; especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. The product label warns consumers that acetaminophen overdosage can potentially cause severe liver damage.

The recall includes the following lots of this product:

- Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg 100 count bottles, NDC 60951-712-70, Lot # 402415NV, Expiry 01/2014; and
- Endocet® (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg 100 count bottles, NDC 60951-712-70, Lot # 402426NV, Expiry 01/2014

Consumers who have the affected product should stop using the product and contact Endo's agent Stericycle at 1-866-723-2681 for return of the product. If consumers have any questions as to whether they possess the affected product, please call the number listed above during the hours of 8 a.m. to 8 p.m. EST Monday through Friday and 8 a.m. to 5 p.m. EST Saturday and Sunday

[Voluntary Recall of Coumadin® 5 mg Tablets initiated by Bristol-Myers Squibb](#)

Bristol-Myers Squibb initiated a voluntary recall of one lot of 1,000 count bottles of Coumadin® (warfarin sodium tablets, USP) 5 mg tablets. The lot number affected is 9H49374A with an expiry date of September 30th, 2012. The recall is a precautionary measure based on the company's testing of tablets from a returned bottle. A single tablet was found to be higher in potency than expected.

Patients who may have 5 mg tablets should not interrupt their therapy but should seek advice from their pharmacist to see if they have tablets originating from the affected lot and if so, should consult their physician for appropriate medical advice.

Health care professionals and customers may call Stericycle, Inc. at 1-866-918-8739 for assistance or report any adverse reactions to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov

[Greenstone Announces Voluntary Nationwide Recall of Citalopram and Finasteride Due to Possible Mislabeling](#)

Greenstone LLC announced a voluntary recall of one lot (lot number F10510058-A) of Citalopram 10 mg tablets, 100-count bottles (used to treat depression) and Finasteride 5 mg tablets, 90-count bottles (used to treat benign prostatic hyperplasia) due to the possibility that incorrect labels have been placed on the bottles.

Bottles labeled as Citalopram Lot # F10510058-A may contain Finasteride. Patients who believe they may have ingested the wrong medication should contact their physician as soon as possible. Women who are, or may become pregnant, should not take or handle Finasteride due to the possible risk of side effects which may cause abnormalities to the external genitalia of a developing male fetus. Citalopram is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or pimozone. Patients who discontinue Citalopram abruptly by inadvertently taking the mislabeled product may experience discontinuation symptoms and/or worsening of depression.

Bottles of either Citalopram or Finasteride with lot number F10510058-A should be returned to the pharmacist.

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Also, any adverse events that may be related to the use of these products should be reported to Pfizer Inc. at 1-800-438-1985 (24 hours a day) or to FDA's Med Watch Program either by www.fda.gov/medwatch/report.htm or by regular mail (postage-paid, pre-addressed form available at www.fda.gov/MedWatch/getforms.htm) or by fax at 1-800-FDA-0178.

Find more information about this recall on FDA's website: <http://www.fda.gov/Safety/Recalls/ucm248552.htm>