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:

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

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:

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.

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

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.

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

On 8/8/2016, Rugby Laboratories recalled Diocto 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: Diocto Syrup (docusate sodium), 60 mg/15 mL
NDC Number: 0536-1001-85

What you should do:

- **Do not continue to use Diocto Syrup (docusate sodium), 60 mg/15 mL if it has been recalled**
- Check your prescription label to see if you have Diocto 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

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:

Recalled Drug: Albuterol Sulfate Syrup, 2 mg/ 5 mL
NDC Number: 0093-0661-16
Lot Numbers: 95113
Expiration Date: 01/2017

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.

Auvi-Q® (epinephrine injection) 0.15mg and 0.3mg (Sanofi)

On Oct. 28, 2015, Sanofi recalled all lots (numbered between 2299596 and 3037230; expiring between March 2016 and December 2016) of both strengths – NDC numbers 00024-5831-02 (0.15mg) and 00024-5833-02 (0.3mg) – for Auvi-Q® (epinephrine injection) auto-injectors. The devices may not deliver accurate doses of epinephrine. More information about the recall is available at: www.auvi-q.com and http://www.fda.gov/Safety/Recalls/ucm469980.htm.

The detailed information of the recalled product is listed below:

Recalled Drug: Auvi-Q (epinephrine injection) (Sanofi)
NDC Numbers: 00024-5831-02 (0.15mg) and 00024-5833-02 (0.3mg)
Lot Numbers: All lots between 2299596 and 3037230
Expiration Dates: March 2016 through December 2016

Sanofi recommends the following:

- As soon as possible, patients should receive a new prescription for an EpiPen® (epinephrine) Auto-Injector or an Adrenaclick® (epinephrine injection) Auto-Injector.
- Auvi-Q devices should not be used unless no alternative is immediately available for an emergency. Patients should not discard recalled devices, however.

- Patients can contact Sanofi at cs@sanofi.com or 1.866.726.6340 Monday through Friday from 8:00 a.m. to 8:00 p.m. ET to arrange for return of recalled Auvi-Q auto-injectors and reimbursement for many out-of-pocket costs for an EpiPen or Adrenaclick.
- Sanofi Medical Information may be contacted by e-mail at: http://www.contactus.sanofi-aventis.us/medicalinquiry.aspx.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch or calling 1.800.332.1088.

Allergan's Blephamide® (sulfacetamide/prednisolone ophthalmic ointment) 10%/0.2%, 3.5Gm tube

On Aug. 24, 2015, Allergan recalled three lots (86258 – expires September 2017, 87189 – December 2017 and 87514 – February 2018) of FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5Gm tube (NDC# 00023-0316-04). After some patients using the ointment reported eye irritation, pain, swelling and other adverse events, particles of plastic from the cap assembly were found to be breaking off into the ointment. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but patients were affected, so it was treated as Class I. More information about the recall is available at: http://www.fda.gov/Safety/Recalls/ucm459485.htm.

The detailed information of the recalled product is listed below:

Recalled Drug: Blephamide (sulfacetamide/prednisolone ophthalmic ointment) 10%/0.2%, 3.5Gm tube (Allergan)
NDC Number: 00023-0313-04
Lot Numbers: 86430 (expires September 2017), 87806 (expires February 2018) and 88147 (expires March 2018)

Allergan advises that:

- Ointment from the recalled lots should not be used.
- Patients who have it should return it to the place of purchase.
- Questions about the recall may be directed to Allergan Medical Inquiries at 800.433.8871, Option 2, Monday through Friday from 8:00 a.m. to 5:00 p.m. PT.
- To inform Allergan of an adverse event, call 800.624.4261, Option 3, Monday through Friday from 8:00 a.m. to 5:00 p.m. CT.
- Adverse events from the use of prescription drugs also should be reported to FDA by calling 800.332.1088 or visiting www.fda.gov/medwatch.

Allergan's FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5Gm tube

On Aug. 24, 2015, Allergan recalled three lots (86258 – expires September 2017, 87189 – December 2017 and 87514 – February 2018) of FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5Gm tube (NDC# 00023- 0316-04). After some patients using the ointment reported eye irritation, pain, swelling and other adverse events, particles of plastic from the cap assembly were found to be breaking off into the ointment. The U.S. Food and Drug Administration (FDA)

has not yet classed the recall, but patients were affected, so it was treated as Class I. More information about the recall is available at:
http://www.fda.gov/Safety/Recalls/ucm459485.htm

Recalled Drug: FML (fluorometholone ophthalmic ointment) 0.1%, 3.5 g (Allergan)
NDC Number: 00023-0316-04
Lot Numbers: 86258 (expires September 2017), 87189 (expires December 2017) and 87514 (expires February 2018)

Allergan recommends that:

- Product from the recalled lots should not be used.
- Patients who have recalled ointment should return it to the place of purchase.
- Questions about the recall may be directed to Allergan Medical Inquiries at 800.433.8871, Option 2, Monday through Friday from 8 a.m. to 5 p.m. PT.
- To inform Allergan of an adverse event, call 800.624.4261, Option 3, Monday through Friday from 8 a.m. to 5 p.m. CT.
- Adverse events from the use of prescription drugs should be reported to FDA by calling 800.332.1088 or visiting www.fda.gov/medwatch

Mylan Mycophenolic Acid Delayed-Release Tablets, 180mg

On May 20, 2015, Mylan Pharmaceuticals recalled one lot (3059043) of **mycophenolic acid delayed-release tablets, 180mg** (NDC# 00378-4201-78). Dissolution results from reserve samples were not within specified values. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Bristol-Myers Squibb extended it to the consumer level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: mycophenolic acid delayed-release tablets, 180mg (Mylan)

NDC Number: 00378-4201-78
Lot Number: 3059043

Expiration Date: August 2016

Mylan recommends that:

- Product from the recalled lots should be quarantined.
- Distributors that received notification from wholesalers return recalled tablets using the labels and forms included with the notice.
- Distributors that did not receive return forms should call Stericycle at 1-855-311-5445 for a documentation packet to return recalled tablets.
- Consumers with recalled tablets should contact the prescriber.
- Adverse events from the use of prescription drugs should be reported to FDA by calling 1- 800-332-1088 or visiting www.fda.gov/medwatch.

Baxter dextrose 5% injection, in 1,000mL Viaflex Plastic Containers

On Mar. 25, 2015, Baxter recalled one lot (C926899) of 5% dextrose in 1,000mL Viaflex containers (NDC# 00338-0017-04) after reports that some containers leaked, some had missing closures or both. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Baxter set it at the consumer level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: dextrose 5% injection in 1,000ml in Viaflex plastic containers (Baxter)
NDC Number: 00338-0017-04
Lot Number: C926899
Expiration Date: Jul. 31, 2015

Baxter recommends the following:

- Product from the recalled lots should not be used.
- Contact the Baxter Healthcare Center for Service at 1.888.229.0001, Monday through Friday, between 7:00 a.m. and 6:00 p.m., CT to arrange for return and replacement of recalled product.
- Questions about the recall may be e-mailed to onebaxter@baxter.com or called to Baxter at 1.800.422.9837, Monday through Friday, between 8:00 a.m. and 5:00 p.m. CT.
- Adverse events from the use of prescription drugs should be reported to FDA by visiting www.fda.gov/medwatch or calling 1.800.332.1088.

Baxter 0.9% Sodium Chloride Injection in 250mL Viaflex Plastic Containers

On Mar. 24, 2015, Baxter recalled eight lots (C963660, C963785, C963884, C964320, C964486, C964890, C965038, C965293) of 0.9% sodium chloride in 250mL Viaflex containers (NDC# 00338- 0049-02) after particles later identified as parts of a pump used to fill the bags were discovered in some containers. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Baxter set it at the consumer level, so it was treated as Class I. More information about the recall is at: http://www.fda.gov/Safety/Recalls/ucm442074.htm

The detailed information of the recalled product is listed below:

Recalled Drug: 0.9% sodium chloride injection in 250mL Viaflex plastic containers (Baxter)
NDC Number: 00338-0049-02
Lot Numbers: C963660, C963785, C963884, C964320, C964486, C964890, C965038, C965293
Expiration Date: Jul. 31, 2016

Baxter recommends that:

- Return and replacement for products from the recalled lots be arranged with the Baxter Healthcare Center for Service at 1.888.229.0001, Monday through Friday, between 7:00 a.m. and 6:00 p.m., CT.
- Patients with products from affected lots notify their physicians and return recalled sodium chloride to the pharmacies that filled it.
- Questions about the recall may be directed to onebaxter@baxter.com or to 1.800.422.9837, Monday through Friday, between 8:00 a.m. and 5:00 p.m. CT.
- 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.

Baxter 5% dextrose injection in 250mL Viaflex Plastic Containers

On Mar. 24, 2015, Baxter recalled two lots (C963413,C963413A) of 5% dextrose in 250mL Viaflex containers (NDC# 00338-0017-02) after particles later identified as parts of a pump used to fill the bags were discovered in some containers. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Baxter set it at the consumer level, so it was treated as Class I. More information about the recall is at: http://www.fda.gov/Safety/Recalls/ucm442074.htm

The detailed information of the recalled product is listed below:

Recalled Drug: 5% dextrose injection in 250ml in Viaflex plastic containers (Baxter)
NDC Number: 00338-0017-02
Lot Number: C963413, C963413A
Expiration Date: Jul. 31, 2016

Baxter recommends the following:

- Return and replacement for products from the recalled lots be arranged with the Baxter Healthcare Center for Service at 1.888.229.0001, Monday through Friday, between 7:00 a.m. and 6:00 p.m., CT.
- Patients with products from affected lots notify their physicians and return recalled dextrose to the pharmacies that filled it.
- Questions about the recall may be directed to onebaxter@baxter.com or to 1.800.422.9837, Monday through Friday, between 8:00 a.m. and 5:00 p.m. CT.
- 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.

Bristol-Myers Squibb Kenalog® - 40 (triamcinolone acetonide injectable suspension 40mg/mL) in 10 mL multi-dose vials

On Apr. 30, 2015, Bristol-Myers Squibb recalled two lots (3G73811 and 4K85461 of **Kenalog®-40 (triamcinolone acetonide injectable suspension 40mg/mL) in 10 mL multi-dose vials** (NDC# 00003-0293-28)**.** A piece of glass was found in one vial from each recalled lot following a

customer's report of a glass piece in a vial. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Bristol-Myers Squibb set it at the user level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: Kenalog-40 in 10mL multi-dose vials (Bristol-Myers Squibb)

NDC Number: 00003-0293-28
Lot Numbers: 3G73811(expiring June 2015) and 4K85461 (expiring September 2016)

Bristol-Myers Squibb advises that:

- Product from the recalled lot not be used.
- Return and replacement of products from the recalled lots be arranged with GENCO at 1-877-319-8962.
- Questions on the recall be directed to Bristol-Myers Squibb Customer Information Center at 1-800-332-2056.
- Adverse events from the use of prescription drugs be reported to FDA at www.fda.gov/medwatch or 1-800-332-1088.

Pfizer Methotrexate Injection 25mg/mL in 2mL vials

On Apr. 23, 2015, Mylan recalled one lot (7801082) of **methotrexate injection 25mg/ml in 2ml vials** after particulates were discovered in retention samples. It was manufactured by Agila Onco Therapies Limited and distributed under the Pfizer label (NDC# 00069-0146-02). The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Mylan set it at the user level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: methotrexate injection 25mg/ml in 2ml vials (Pfizer)

NDC Number: 00069-0146-02
Lot Number: 7801082

Expiration Date: July 2015

Mylan advises that:

- Product from the recalled lot should not be used.
- Letters are being sent from Mylan to inform customers about return procedures.
- Questions on the recall go to Mylan Customer Relations at customer.service@mylan.com or 1-800-796-9526 Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.
- Adverse events from the use of prescription drugs should be reported to FDA at www.fda.gov/medwatch or 1-800-332-1088.

Hospira 0.5% Bupivacaine Injection, 30mL in Preservative-Free, Single-Dose Vials

On Apr. 23, 2015, Hospira recalled one lot (38-515-DK) of 0.5% **bupivacaine** injection, 30mL in preservative-free, single-dose vials (NDC# 00409-1162-02) after a report that iron oxide particles were seen in the solution and glass of one vial. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Hospira set it at the user level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: 0.5% bupivacaine injection, 30mL in preservative-free, single-dose vials (Hospira)

NDC Number: 00409-1162-02
Lot Number: 38-515-DK

Expiration Date: Feb. 1, 2016

Hospira recommends that:

- Product from the recalled lots should not be used.
- Stericycle should be contacted at 1-866-918-8770, Monday through Friday, between 8:00 a.m. and 5:00 p.m. ET, to arrange for return and replacement of recalled product.
- Questions about the recall should be directed to Hospira Medical Communications at 1- 800-615-0187 or medcom@hospira.com.
- Adverse events from the use of prescription drugs should be reported to FDA by calling 1- 800-332-1088 or visiting www.fda.gov/medwatch.

Baxter 0.9% sodium chloride 500 mL Viaflex containers

On Mar. 25, 2015, Baxter recalled three lots (C926873, C928630, C929844) of **0.9% sodium chloride in 500mL Viaflex containers** (NDC# 00338-0049-03) after reports that some containers leaked, some had missing closures or both. The U.S. Food and Drug Administration (FDA) has not yet classed the recall, but Baxter set it at the consumer level, so it was treated as Class I.

The detailed information of the recalled product is listed below:

Recalled Drug: 0.9% sodium chloride injection in 500mL Viaflex plastic containers
NDC Number: 00338-0049-03
Lot Numbers: C926873, C928630, C929844

Manufacturer: Baxter

Baxter recommends that:

- Return and replacement for products from the recalled lot be arranged with the Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between 7:00 a.m. and 6:00 p.m., CT.
- Patients with products from affected lots notify their physicians and return recalled sodium chloride to the pharmacies that filled it.
- Questions about the recall may be directed to onebaxter@baxter.com or to 1-800-422-9837, Monday through Friday, between 8:00 a.m. and 5:00 p.m. CT.
- 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.