Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 29, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT/Supervisor
Food Protection Program

SUBJECT: Sanofi US – RECALL [Drug]

AFFECTED PRODUCT: **Auvi-Q® (epinephrine injection, USP)**

SUMMARY: **Unclassified Recall; The recall has been initiated because the products have been found to potentially have inaccurate dosage delivery.**

The recall involves all Auvi-Q currently on the market and includes both the 0.15 mg and 0.3 mg strengths for hospitals, retailers and consumers. This includes lot number 2299596 through 3037230, which expire March 2016 through December 2016.

Auvi-Q was distributed throughout the United States via wholesalers, pharmacies and hospitals.

SUGGESTED ACTION: **For consumer inquiry only. Customers with questions regarding this recall can go to www.Auvi-Q.com and call 1-866-726-6340 Monday through Friday 8 a.m. to 8 p.m. ET for information about how to return their Auvi-Q devices. Customers may also email cs@sanofi.com.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Recall: Firm Press Release
Sanofi US Issues Voluntary Nationwide Recall of Auvi-Q® Due to Potential Inaccurate Dosage Delivery
FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

October 28, 2015

Contact

Consumers

Sanofi US.
1-800-981-2491

Media

Karen Sutherland
USMediaRelations@Sanofi.com
1-908-989-0726
Firm Press Release
View Product Photos

Bridgewater, N.J. - Sanofi US is voluntarily recalling all Auvi-Q® (epinephrine injection, USP). The recall involves all Auvi-Q currently on the market and includes both the 0.15 mg and 0.3 mg strengths for hospitals, retailers and consumers. This includes lot number 2299596 through 3037230, which expire March 2016 through December 2016. The products have been found to potentially have inaccurate dosage delivery.

If a patient experiencing a serious allergic reaction (i.e., anaphylaxis) did not receive the intended dose, there could be significant health consequences, including death because anaphylaxis is a potentially life-threatening condition. As of October 26, 2015, Sanofi has received 26 reports of suspected device malfunctions in the US and Canada. None of these device malfunction reports have been confirmed. In these reports, patients have described symptoms of the underlying hypersensitivity reaction. No fatal outcomes have been reported among these cases.

Auvi-Q (epinephrine injection, USP) is used to treat life-threatening allergic reactions (anaphylaxis) in people who are at risk for or have a history of these reactions. Auvi-Q is packaged with two active devices and one trainer device in a corrugate box. Auvi-Q was distributed throughout the United States via wholesalers, pharmacies and hospitals. All Auvi-Q is being recalled.

Sanofi US is notifying its distributors and customers who include doctors, pharmacies, wholesalers and other customers in the supply chain by letter, fax, email and phone calls and is arranging for return and reimbursement of all recalled products.

Customers with questions regarding this recall can go to www.Auvi-Q.com and call 1-866-726-6340 Monday through Friday 8 a.m. to 8 p.m. ET for information about how to return their Auvi-Q devices. Customers may also email cs@sanofi.com. Sanofi US will provide reimbursement for out of pocket costs incurred for the purchase of new epinephrine auto-injectors with proof of purchase.

Customers should immediately contact their healthcare provider (HCP) for a prescription for an alternate epinephrine auto-injector. In the event of a life-threatening allergic reaction (anaphylaxis), patients should only use their Auvi-Q device if another epinephrine auto-injector is not available, and then call 911 or local medical emergency services. Customers should contact their physician or HCP if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: http://www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form http://www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Sanofi US is committed to patient safety and the quality of Auvi-Q, and will continue to work closely with customers and regulatory authorities to resolve this issue in a timely manner.

Important Safety Information

Auvi-Q is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after use. Each Auvi-Q contains a single dose of epinephrine. **Auvi-Q should only be injected into your outer thigh**. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY. If you accidentally inject Auvi-Q into any other part of your body, seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

If you take certain medicines, you may develop serious life-threatening side effects from epinephrine. Be sure to tell your doctor about all the medicines you take, especially medicines for asthma. Side effects may be increased in patients with certain medical conditions, or who take certain medicines. These include asthma, allergies, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure, and heart disease.

The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness, or anxiety. These side effects go away quickly, especially if you rest.

You are encouraged to report negative side effects of prescription drugs. In the US, contact the FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for Full Prescribing Information.

About Sanofi US

Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi is the holding company of a consolidated group of subsidiaries and operates in the United States as Sanofi US. For more information on Sanofi US, please visit http://www.sanofi.us and http://www.news.sanofi.us/social-media or call 1-800-981-2491.

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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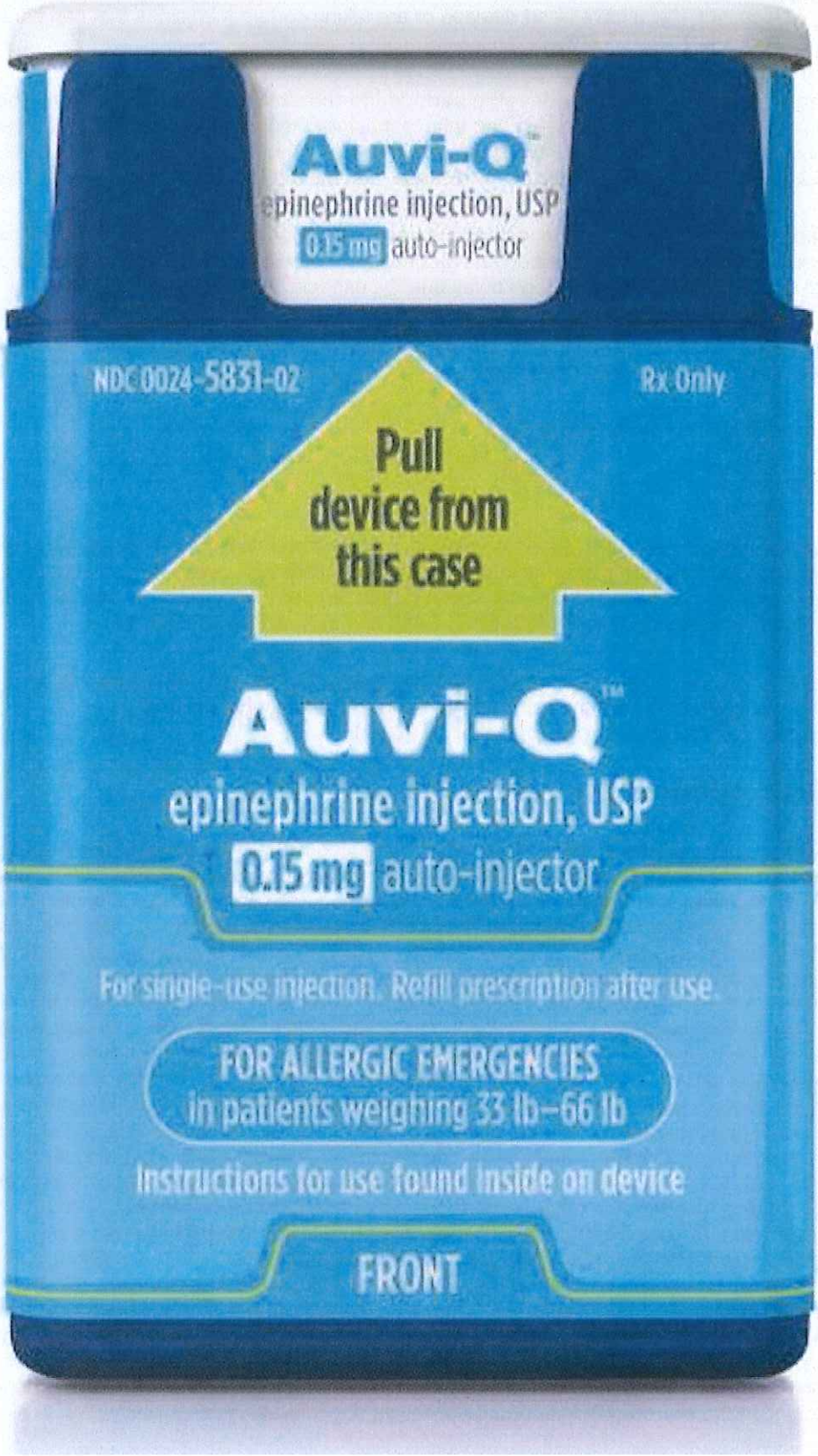
Product Photos




Auvi-Q™
epinephrine injection, USP
0.3 mg auto-injector
NDC 0024-5833-02
Rx Only
Pull device from this case
Auvi-Q™
epinephrine injection, USP
0.3 mg auto-injector
For single-use injection. Refill prescription after use.
FOR ALLERGIC EMERGENCIES in patients weighing over 66 lb
Instructions for use found inside on device
FRONT