To: OESCommunications@cattco.org<mailto:OESCommunications@cattco.org>
Subject: Fw: FDA MedWatch - Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery

Good Afternoon,

If you use Auvi-Q Epinephrine Auto injectors, please see recall information below.

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From: FDA MedWatch [mailto:fda@service.govdelivery.com]
Sent: Thursday, October 29, 2015 9:10 AM
To:
Subject: FDA MedWatch - Auvi-Q (epinephrine injection, USP): Recall - Potential Inaccurate Dosage Delivery Auvi-Q (epinephrine injection, USP):

Recall - Potential Inaccurate Dosage Delivery AUDIENCE: Pharmacy, Patient ISSUE: 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. See the Press Release for product photos.
http://www.fda.gov/Safety/Recalls/ucm469980.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

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.

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.

BACKGROUND: 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.

RECOMMENDATION: 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 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report Online:
www.fda.gov/MedWatch/report<http://www.fda.gov/MedWatch/report>
Download form 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

Read the MedWatch safety alert, including a link to the Press Release, at:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm470010.htm