NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the clinician should consider new clinical information, as available and applicable.

PBM-2016-09 **SEPTEMBER 9, 2016**

ITEM: **Eye Wash/Eye Irrigating Solutions Distributed by Major Pharmaceuticals and Rugby Laboratories – Recall Due to Microbial Contamination**

SPECIFIC INCIDENT(S): United Exchange Corp., a primary source vendor of Rugby® Eye Irrigating Solution and Major® Eye Wash, is voluntarily recalling certain lots due to **microbial contamination**.

GENERAL INFORMATION:

- Eye Wash/Eye Irrigating Solution consists of a purified water solution used to flush foreign material from the eye to relieve symptoms such as irritation, stinging, or itching.
- Use of a contaminated product may result in potentially sight-threatening eye infection.
- Affected products and lots are included below:

Product Description	NDC Number	Lot Number	Expiration Date
Major EyeWash	0904-6491-20	G15905	2018.10
Major EyeWash	0904-6491-20	G15906	2018.10
Major EyeWash	0904-6491-20	G15907	2018.10
Major EyeWash	0904-6491-20	G15910	2018.11
Major EyeWash	0904-6491-20	G15911	2018.11
Major EyeWash	0904-6491-20	G15912	2018.11
Major EyeWash	0904-6491-20	G16901	2019.01
Major EyeWash	0904-6491-20	G16902	2019.01
Major EyeWash	0904-6491-20	G16903	2019.01
Major EyeWash	0904-6491-20	G16905	2019.02
Major EyeWash	0904-6491-20	G16906	2019.02
Major EyeWash	0904-6491-20	G16907	2019.02
Major EyeWash	0904-6491-20	G16910	2019.03
Major EyeWash	0904-6491-20	G16911	2019.03
Rugby EyeWash	0536-1083-97	G15908	2018.10
Rugby EyeWash	0536-1083-97	G15909	2018.11
Rugby EyeWash	0536-1083-97	G16904	2019.01
Rugby EyeWash	0536-1083-97	G16908	2019.02
Rugby EyeWash	0536-1083-97	G16912	2019.03
Rugby EyeWash	0536-1083-97	G16913	2019.03

- This alert is an extension of the product sequestration actions in **Product Recall Office Log # 11107** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).
- Providers should continue to report any adverse reactions with the use of Rugby® Eye Irrigating Solution and Major® Eye Wash by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms.

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch- online.htm, or by mail).

ACTIONS:

PROVIDER NOTIFICATION:

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., **primary care providers, ophthalmologists, optometrists, and pharmacy staff, including contract providers**, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

PATIENT NOTIFICATION:

- **Chief of Pharmacy:** Within 10 business days of issue (due 9/23/2016):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration. CMOP data will be provided by a CMOP representative to Pharmacy Chiefs.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
      - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc .
      - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with instructions on the following:
      - How to return the product being recalled to the pharmacy.
      - How to obtain a new supply of product.
      - Patients should not continue to use the product until they obtain replacement product.
      - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
  - Communicate to PBM/VAMedSAFE that all patient notification actions

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA

REFERENCE(S):

United Exchange Corp. Issues Voluntary Nationwide Recall of Eye Wash/Eye Irrigating Solutions Distributed by Major Pharmaceuticals and Rugby Laboratories Due to Microbial Contamination. http://www.fda.gov/Safety/Recalls/ucm519517.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery . Accessed September 8, 2016.

ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.