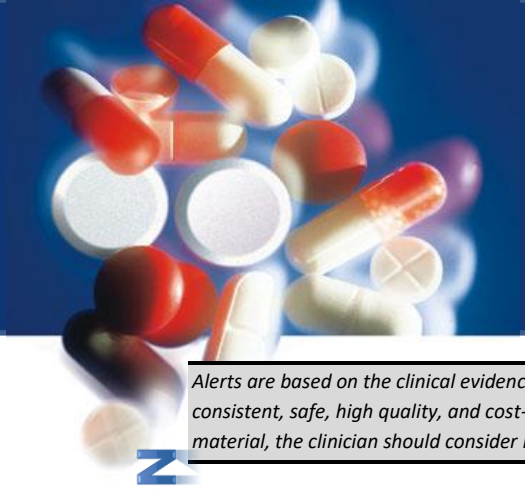

Alerts are based on the clinical evidence available at the time of publication. Recommendations are intended to assist practitioners in providing consistent, safe, high quality, and cost-effective drug therapy. They are not intended to interfere with clinical judgment. When using dated material, the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

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

PBM-2023-12 **May 9, 2023**

ITEM: **Akorn Multiple Products Recall**

SPECIFIC INCIDENT(S):

Akorn Operating Company LLC has ceased and shutdown all operations due to bankruptcy. The Akorn Trustee is initiating a voluntary recall of various within-expiry human and animal products as a result of the closures and discontinuation of the Quality activities.

GENERAL INFORMATION:

- Per manufacturer: *"The discontinuation of the Quality program would result in the company's inability to assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess which render the products adulterated."*
- According to the manufacturer, *"further distribution or use of any remaining product on the market should cease immediately."*
- Affected products include:
  - AKORN Attachment I: List of Human Products
  - AKORN - Attachment II – List of Veterinary Products
- This alert is an extension of the product sequestration actions from NCPS in Safety Record Number SR-45628 available at: VA Alerts & Recalls Live . (Note: Only active users will be able to use the link to view the post.)
- Providers should continue to report any adverse reactions with the use of potentially affected products by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. 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/index.cfm , 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 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 5/23/2023):

NATIONAL PBM PATIENT LEVEL RECALL COMMUNICATION

- Determine whether the affected product(s) was dispensed to any patient(s) for home use. CMOP data will be provided by CMOP representatives to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact the patient(s) who may have received the affected product(s) for home use by letter (or other means).
    - A sample letter can be found at: https://dvagov.sharepoint.com/:w:/r/sites/VHAPBM/Formulary/_layouts/15/Doc.aspx?sourcedoc=%7BB49A9262-448D-4BA9-BD67-46D201C8D379%7D&file=ASA%20Recall%20Patient%20Letter%20Template.doc&action=default&mobileredirect=true.
    - This template can be altered according to site-specific needs.
  - Provide patient(s) who have received the affected product with a replacement product and instructions on the following:
    - Advise patients with affected lot number(s) on how to obtain replacement**.** Local sites will need to work with patients to get them what is needed for their care in the most expedient way.
    - Patients should discontinue use of the affected product until they obtain replacement product.
    - When the correct product is received, patients should begin using the new product and return any unused old product.
- Communicate to PBM/VAMedSAFE that all impacted patients have been contacted via the NCPS Alerts & Recalls System available at: VA Alerts & Recalls Live . (Note: Only active users will be able to use the link.)

SOURCE: McKesson; FDA

REFERENCE(S):

1. McKesson. Urgent Drug Recall. RC 23-073. 4/27/2023.
2. McKesson. Urgent Drug Recall. RC 23-073A. 5/3/2023.
3. McKesson. Urgent Drug Recall. RC 23-073B. 5/8/2023.
4. FDA. Company Announcement: UPDATE - Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry?utm_medium=email&utm_source=govdelivery . Accessed 5/4/2023.

ATTACHMENT(S): None.

CONTACT(S): Pharmacy Benefits Management Services (PBM) at patientlevelrecalls@va.gov.