DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown

4/26/2023

April 26, 2023 – Gurnee, IL, Akorn Operating Company LLC has filed Chapter 7 bankruptcy on February 23, 2023. In connection with that filing, the company has ceased and shutdown all operations and terminated all its employees of all domestic US Sites. 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 of these marketed products. (Refer to Attachment I and II). The discontinuation of the Quality program means the company will not be able to support or guarantee that the products will meet all intended specifications through the labeled shelf life of the product. Further distribution or use of any remaining product on the market should cease immediately.

Risk Statement: 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. While specific risks to patients, from use of these adulterated products, cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products. Akorn has not received any reports of adverse events related to this recall.

The affected products are listed in Attachment I (human drugs) and II (animal drugs) of this release. The products were distributed nationwide to **Wholesalers, Retailers, Manufacturers, Medical Facilities, and Repackagers and via the Internet to Consumers.**

Akorn is notifying its distributors and direct consignees by direct mailing and is requesting they further notify their customers/consumers/retailers. Akorn is requesting destruction of any recalled products. Consumers/distributors/retailers that have products which are being recalled should discard and contact their doctor.

Consumers with questions regarding this recall can contact Akorn at (800) 932-5676 during normal business hours (8am – 5pm CDT) Monday – Friday. A qualified medical professional will return your call within one business day. Consumers should contact their physician, their healthcare provider or veterinarian if they, or animals in their care, have experienced any problems that may be related to taking or using these drug products.

For human drug products, adverse reactions or quality problems experienced with the use of these products 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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form 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.

For a list of human products you may access: https://www.fda.gov/media/167552/download

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry-due