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Akorn issues voluntary nationwide recall of various human and animal drug products within expiry due to company shutdown

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Akorn has posted a full lot recall of various human drug products.

About this recall:

Akorn Operating Company filed Chapter 7 bankruptcy on Feb. 23, 2023. In connection with that filing, the company has ceased and shut down all operations and terminated all its employees of all domestic U.S. sites. The Akorn Trustee is initiating a voluntary recall of various within-expiry human products as a result of the closures and discontinuation of the Quality program activities of these marketed products. 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.

What this means to you:

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) of the FDA press release. Only products listed in the attachment are affected by the recall. Products not included in the press are continuing to be monitored under a Quality program and will remain on the market. 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 carry products that are being recalled should discard and contact their doctor.

Consumers with questions regarding this recall can contact Akorn at **800.932.5676**, Monday–Friday, 8 a.m.–5 p.m. Central Daylight Time (CDT). A qualified medical professional will return your call within one business day. Consumers should contact their physician or their health care provider if they have experienced any problems that may be related to taking or using these drug products.