COMPANY ANNOUNCEMENT

Mylan Pharmaceuticals Initiates Voluntary Nationwide Recall of One Lot of Alprazolam Tablets, USP C-IV 0.5 mg, Due to the Potential of Foreign Substance

Summary

Company Announcement Date:

October 25, 2019

FDA Publish Date:

October 26, 2019

Product Type:

Drugs

Reason for Announcement:

Potential presence of foreign substance

Company Name:

Mylan Pharmaceuticals Inc.

Brand Name:

Mylan Pharmaceuticals Inc.

Product Description:

Alprazolam Tablets, USP C-IV 0.5 mg

Company Announcement

Mylan Pharmaceuticals Inc. is conducting a voluntary nationwide recall of one lot (see table below) of Alprazolam Tablets, USP C-IV 0.5 mg, to the consumer/user level. This lot is being recalled due to the potential presence of foreign substance. Clinical impact from the foreign material, if present, is expected to be rare, but the remote risk of infection to a patient cannot be ruled out. To date, Mylan has not received any adverse events related to this batch.

Alprazolam Tablets are indicated for the management of anxiety disorder, the short-term relief of symptoms of anxiety, and the treatment of panic disorder, with or without agoraphobia.

Alprazolam Tablets, USP C-IV 0.5 mg, are packaged in bottles of 500. This batch was distributed in the U.S. between July 2019 and August 2019. The recalled lot is as follows:

NDC	Product Description and Strength	Size	Lot number	Expiry
0378-4003-05	Alprazolam Tablets, USP C-IV 0.5 mg	Bottles of 500	8082708	September 2020

Mylan has notified its distributors and customers by letter and is arranging for return of all recalled products. Following are actions for wholesalers, retailers and consumers:

- **Wholesaler:** Immediately examine your inventory, quarantine and discontinue distribution of these lots. In addition, if you have further distributed the product, please identify your retail level customers and provide a list of customers via Microsoft excel file to mylan5924@stericycle.com (mailto:mylan5924@stericycle.com) within 10 business days. Stericycle will notify your retail level customers that received the affected batches.
- **Retailer:** Immediately examine your inventory, quarantine and discontinue distribution of these lots. Additionally, if you have further distributed the product, please identify the consumer and notify them immediately of this product recall. The consumer should be instructed to contact Stericycle at 1-888-843-0255 for the documentation packet to return the product.
- **Consumer:** Please contact Stericycle at 1-888-843-0255 for the documentation packet to return product to Stericycle.

Consumers with questions regarding this recall can contact Mylan Customer Relations at 800.796.9526 or customer.service@mylan.com (mailto:customer.service@mylan.com), Monday through Friday from 8 a.m. – 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.
Adverse reactions or quality problems experienced with the use of this product 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 (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) 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

Company Contact Information

Consumers:

Stericycle

1-888-843-0255

Product Photos

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