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

October 25, 2019

MORGANTOWN, W.Va., Oct. 25, 2019 /PRNewswire/ -- 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 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, 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: 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.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's

easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

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SOURCE Mylan N.V.

Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813