Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: February 20, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: A subsidiary of Mylan Inc., Agila Specialties Private Limited - Recall [Drug]

AFFECTED PRODUCT: **Etomidate Injection 2 mg/mL – 10 mL and 20 mL**

SUMMARY: **Unclassified Recall; The recall is due to the potential for small black particles, identified as paper shipper labels, to be present in individual vials; the potential for missing lot number and/or expiry date on the outer carton, and the potential for illegible/missing lot number and expiry on individual vials.**

All 10 lots of Etomidate Injection 2 mg/ml bear a Pfizer label, and are listed below:

NDC	Size	Lot #	Expiration
0069-0006-03	20 mL	5001012	Sep-14
		5000927	Jun-14
		5000931	Jun-14
		5000936	Jun-14
		5000942	Jun-14
		5001071	Oct-14
		5001040	Sep-14
0069-0006-01	10 mL	5001023	Sep-14
		5000983	Aug-14
		5000986	Aug-14

The recalled lot was distributed <u>nationwide</u> to distributors, retailers, hospitals, pharmacies, and/or clinics.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Mylan Customer Service with questions at 800.848.0462 on Monday through Friday between 8 a.m. and 5 p.m. EST.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Agila Specialties Private Limited Initiates Voluntary Nationwide Recall of 10 Lots of Etomidate Injection 2 mg/mL – 10 mL and 20 mL due to the Presence of Particulate Matter and/or Illegible and Missing Lot Number and/or Expiry Date

Contact:
Consumer:
800.848.0462

Media:
Nina Devlin
724.514.1968

FOR IMMEDIATE RELEASE — February 19, 2014 – PITTSBURGH, PA-Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Agila Specialties Private Limited is conducting a voluntary nationwide recall to the hospital/user level of 10 lots of Etomidate Injection 2 mg/mL – 10 mL and 20 mL (see lot breakdown below). The 10 lots were manufactured by Agila Specialties Polska sp.zo.o in Warsaw, Poland. All of the products bear a Pfizer label. Agila Specialties Private Limited initiated the recall on Feb. 13, 2014, due to the potential for small black particles, identified as paper shipper labels, to be present in individual vials; the potential for missing lot number and/or expiry date on the outer carton, and the potential for illegible/missing lot number and expiry on individual vials. Intravenous administration of particles may lead to impairment of microcirculation, phlebitis, infection, embolism and subsequent infarction. Mylan and Pfizer have not received any reports of adverse events related to the recalled product to date.

Etomidate is a hypnotic drug without analgesic activity. It is indicated by intravenous injection for the induction of general anesthesia. Etomidate is also indicated for the supplementation of subpotent anesthetic agents. Etomidate 2 mg/mL is packaged in glass vials in 10 mL and 20 mL volumes. Product was distributed Nationwide to distributors, retailers, hospitals, pharmacies, and/or clinics. The affected Etomidate lots include the following:

Etomidate Injection 2 mg/mL

NDC	Size	Lot #	Expiration
0069-0006-03	20 mL	5001012	Sep-14
		5000927	Jun-14
		5000931	Jun-14
		5000936	Jun-14
		5000942	Jun-14
		5001071	Oct-14

		5001040	Sep-14
0069-0006-01	10 mL	5001023	Sep-14
		5000983	Aug-14
		5000986	Aug-14

Mylan notified its customers of the recall by letter on Feb.13, 2014. Distributors, retailers, hospitals, pharmacies, or clinics that have product which is being recalled should stop use and discontinue distribution.

Consumers with questions regarding this recall can contact **Mylan Customer Service with questions at** 800.848.0462 **on Monday through Friday between 8 a.m. and 5 p.m. EST**. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or 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. Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside mylan.com