Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: December 21, 2012

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

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

SUBJECT: Mylan Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Mylan Institutional business is conducting a voluntary nationwide recall to the retail level of three lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg (Lots 3037841, 3040859 and 3042573). The three lots were manufactured by Qualitest Pharmaceuticals, and Mylan Institutional repackaged and distributed the product in unit dose (CD100) under the UDL Laboratories, Inc. (n/k/a Mylan Institutional Inc.) label; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. As indicated in Qualitest Pharmaceuticals' announcement, unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Voluntary Product Recall Initiated by Qualitest Pharmaceuticals Impacts Three Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg Repackaged and Distributed by Mylan Institutional

Contact
Consumer:
(800) 848-0462

Media
Nina Devlin
(724) 514-1968

FOR IMMEDIATE RELEASE - December 20, 2012 - Mylan Inc. (Nasdaq: MYL) today announced that its Mylan Institutional business is conducting a voluntary nationwide recall to the retail level of three lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg (Lots 3037841, 3040859 and 3042573). The three lots were manufactured by Qualitest Pharmaceuticals, and Mylan Institutional repackaged and distributed the product in unit dose (CD100) under the UDL Laboratories, Inc. (n/k/a Mylan Institutional Inc.) label. Qualitest Pharmaceuticals first initiated the recall on Dec. 6, 2012, due to the possibility that a small number of tablets from the affected lots may exceed the weight requirement and could exceed the label claim potency requirements for the ingredients hydrocodone bitartrate and acetaminophen. As indicated in Qualitest Pharmaceuticals' announcement, unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day.

Additional information can be found at http://www.fda.gov/Safety/Recalls/ucm331218.htm[1]. Consumers who have the affected lots can contact Mylan Customer Service with questions at 800.848.0462 on Monday through Friday between 8 a.m. and 5 p.m. EST.

About Mylan

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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third 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 150 countries and territories. Our workforce of more than 18,000 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

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