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: September 24, 2012

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

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

SUBJECT: Watson Laboratories, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Voluntary nationwide recall for two lots of Hydrocodone Bitartrate and APAP Tablets, USP 10 mg/500 mg may contain higher than indicated amounts of the ingredients Hydrocodone Bitartrate and/or Acetaminophen; 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. Consumers who have lots 519406A or 521759A should contact their pharmacy or health care professional. Consumers who are unsure if they have the affected lot numbers should consult their pharmacy or health care professional. 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.

Watson Issues Voluntary Nationwide Recall of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg Due to the Potential for Oversized and Superpotent Tablets

Contact
Consumer:
1-800-272-5525

Media:
Charlie Mayr
(862) 261-8030

FOR IMMEDIATE RELEASE - September 20, 2012 - WatsonLaboratories, Inc. today issued a voluntary nationwide recall for two lots of Hydrocodone Bitartrate and APAP Tablets, USP 10 mg/500 mg. A customer complaint was received for tablets that were thicker and darker shade than the other tablets. It is possible that some tablets from lots 519406A and 521759A exceed the weight specification and may contain higher than indicated amounts of the ingredients Hydrocodone Bitartrate and/or Acetaminophen.

Unintentional ingestion of excessive amounts of acetaminophen may potentially result in an adverse event, including 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. The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death. Unintentional ingestion of excessive amounts of hydrocodone may result in an adverse event, including an increase in the severity or frequency of side effects, such as sedation or respiratory depression, particularly in patients who are elderly, have severe kidney or liver impairment, or are also taking interacting medications, for example other sedating medications or certain antidepressants. No reports of injuries related to the recalled product have been received to date.

The recall includes the following product lots:

- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg, 500 count NDC 00591-0540-05, Lot Numbers 519406A and 521759A both with the expiry date April 2014.

Hydrocodone bitartrate and acetaminophen 10 mg/500 mg tablets are indicated for the relief of moderate to moderately severe pain. The affected lots were distributed between 6/27/2012 and 7/18/2012 to wholesale distributors and retail pharmacies nationwide. The lot numbers can be found on the manufacturer's bottle label. Hydrocodone Bitartrate and Acetaminophen Tablets are approximately 0.6 inches in length, blue, bisected capsule shaped, with "Watson 540" de-bossed on one side of the tablet.

Consumers who have lots 519406A or 521759A should contact their pharmacy or health care professional. Consumers who are unsure if they have the affected lot numbers should consult their pharmacy or health care professional.

Pharmacists and wholesalers are asked to check their inventories for lots 519406A or 521759A segregate any material from the lots, and to contact GENCO Pharmaceutical Services at 1-800-950-5479 for instructions on product return. Pharmacies that received lots 519406A or 521759A will receive a copy of this press release with their recall notification information. In order to make your patients aware of this recall, please post the enclosed press release prominently in the pharmacy area.

For more information please contact Watson Laboratories at 1-800-272-5525; Monday through

Friday between the hours of 8 a.m. and 5 p.m. EST. Reports of adverse reactions or quality problems can also be reported to Watson Laboratories at 1-800-272-5525.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either on line, by regular mail, or by fax.

- **Online: www.fda.gov/medwatch/report.htm1**[1]
- **Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm2**[2]**. Mail to address on the pre-addressed form.**
- **Fax: 1-800-FDA-0178**

This voluntary recall is being made with the knowledge of the U.S. Food and Drug Administration.

About Watson Pharmaceuticals, Inc.

Watson Pharmaceuticals, Inc. is an integrated global specialty pharmaceutical company. The Company is engaged in the development, manufacturing, marketing and distribution of generic pharmaceuticals and specialized branded pharmaceutical products focused on Urology and Women's Health. Watson has operations in many of the world's established and growing international markets.

For press release and other company information, visit Watson Pharmaceuticals' Web site at http://www.watson.com[3].

Forward-Looking Statement

Any statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Watson's current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Watson disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Watson's current expectations depending upon a number of factors affecting Watson's business. These factors include, among others, the impact of competitive products and pricing; market acceptance of and continued demand for Watson's products; difficulties or delays in manufacturing; the difficulty of predicting the timing or outcome of FDA or other regulatory agency approvals or actions, if any; and other risks and uncertainties detailed in Watson's periodic public filings with the Securities and Exchange Commission, including but not limited to Watson's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and Watson's Annual Report on Form 10-K for the year ended December 31, 2011. Except as expressly required by law, Watson disclaims any intent or obligation to update these forward-looking statements.

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Photo: Product Labels[6]