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 11, 2012

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

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

SUBJECT: Qualitest Recall

SUGGESTED ACTION: **Unclassified Recall; Nationwide retail level recall for one lot of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The affected lot, C1440512A, was distributed between May 14 and Aug. 3, 2012 to wholesale distributors and retail pharmacies nationwide. Detail 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.

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

Contact:
Consumer:
1-800-444-4011

Media:
Blaine Davis
610-459-7158

Kevin Wiggins
610-459-7281

FOR IMMEDIATE RELEASE - September 10, 2012 - Qualitest, a subsidiary of Endo Health Solutions (Nasdaq: ENDP), today issued a voluntary, nationwide retail level recall for one lot of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg.

The recall includes the following product lot:

- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg, NDC 0603-3888-21, 100 count, Lot Number C1440512A, expiry date 12/13.

It is possible that some tablets from lot C1440512A exceed the weight specification and could be super-potent for the ingredients Hydrocodone Bitartrate and Acetaminophen.

Bottles from the affected lot may contain tablets that have a higher dosage of acetaminophen, and as a result, it is possible that consumers could take more than the intended acetaminophen dose. 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. The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death. Taking a higher dose of hydrocodone than intended could result in 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 injuries have been reported to date.

Hydrocodone bitartrate and acetaminophen 10 mg/500 mg tablets are indicated for the relief of moderate to moderately severe pain. The affected lot, C1440512A, was distributed between May 14 and Aug. 3, 2012 to wholesale distributors and retail pharmacies nationwide. The lot number can be found on the side of the manufacturer's bottle. Hydrocodone Bitartrate and Acetaminophen Tablets are approximately 16.51 mm in length, pink, capsule-shaped tablets, with *"3600"* debossed on one side of the tablet and *"V"* on the other.

Consumers who have lot C1440512A should contact Qualitest at 1-800-444-4011. Consumers who are unsure if they have the affected lot number should consult their pharmacy or health care professional.

Pharmacists and wholesalers are asked to check their inventories for lot C1440512A, segregate any material from the lot, and to contact MedTurn at 1-800-967-5952 for instructions on product return. Pharmacies that received lot C1440512A 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 Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8 a.m. and 5 p.m. CST. Reports of adverse reactions or quality problems can also be reported to Qualitest at 1-800-444-4011; Monday through Friday between the hours of 8 a.m. and 5 p.m. CST.

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