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 7, 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; 101 lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg are being recalled due to a number of tablets from the affected lots may exceed the weight requirement and could exceed the label claim potency requirements for the ingredients of hydrocodone bitartrate and 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. The affected lots, were distributed between Feb. 20, 2012 and Nov. 19, 2012 to wholesale distributors and retail pharmacies nationwide. 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.

Qualitest Issues Voluntary, Nationwide Recall of 101 Lots 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
1-610- 459-7158

FOR IMMEDIATE RELEASE December 6, 2012 - Qualitest, a subsidiary of Endo Health Solutions, (Nasdaq: ENDP) today issued a voluntary nationwide recall for 101 lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10 mg/500 mg. This includes product with the following NDC numbers and lot numbers beginning with the letter "C".

NDC Number	Bottle Count
0603-3888-16	30
0603-3888-20	60
0603-3888-02	90
0603-3888-21	100
0603-3888-22	120
0603-3888-26	150
0603-3888-04	180
0603-3888-28	500
0603-3888-32	1000

It is possible that a number of tablets from the affected lots may exceed the weight requirement and could exceed the label claim potency requirements for the ingredients of hydrocodone bitartrate and acetaminophen. Hydrocodone bitartrate and acetaminophen 10mg/500 mg tablets are indicated for the relief of moderate to moderately severe pain.

Bottles from the affected lots 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.

The affected lots, were distributed between Feb. 20, 2012 and Nov. 19, 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.

It is very important that consumers do not exceed the maximum daily dose in the prescribing information for this product (no more than 6 tablets per day) and are fully aware of any other prescription or over-the-counter medications they may be taking that contain acetaminophen. If there is any doubt, a consumer should consult with their health care professional.

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.

Consumers who have the affected lots should contact Qualitest at 1-800-444-4011. Consumers who are unsure if they have the affected lot numbers or have any concerns about their product should consult their pharmacy or health care professional.

Pharmacists and wholesalers are asked to check their inventories for the affected lots, segregate any material from the lots, and to contact MedTurn at 1-800-967-5952 for instructions on product return. Pharmacies that received the affected lots will receive a copy of this press release with their recall notification information to be prominently posted 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.

- 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

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

About Qualitest

Founded in 1983, Qualitest provides affordable, high-quality generic pharmaceuticals. Featuring a current portfolio exceeding 600 products, the company has grown significantly since its inception and is now ranked in the top ten among all suppliers of generics, based on total prescriptions filled. Qualitest is a wholly owned subsidiary of Endo Health Solutions (Nasdaq: ENDP), a U.S.-based, specialty healthcare solutions company, focused on high-value branded products and specialty generics (www.endo.com[3]).

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