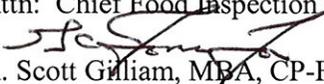




Mitchell E. Daniels, Jr.
Governor

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

DATE: June 27, 2011
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Qualitest Pharmaceuticals Recall

SUGGESTED

ACTION: Unclassified Recall; Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, and Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg. This recall was initiated because an individual bottle of Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, 500 count was found incorrectly labeled with a Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg, 1000 count label, printed with Lot Number C0590909B. Lots C0390909A, C0400909A, C0410909A used the same stock inventory of labels as Lot C0590909B and are potentially impacted; Information provided in case of consumer inquiry.

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. These lots were distributed between November 13, 2009 and April 9, 2010 to wholesale and retail pharmacies nationwide (including Puerto Rico). Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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 Pharmaceuticals Issues Voluntary, Nationwide Retail Level Recall of Four Lots of Butalbital, Acetaminophen, and Caffeine Tablets, USP 50mg/325mg/40mg and Four Lots of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg

Contact:

Consumer:
800-444-4011

Media:
Kevin Wiggins
610-459-7281

FOR IMMEDIATE RELEASE - June 24, 2011 - Qualitest Pharmaceuticals today issued a voluntary nationwide retail level recall of Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, and Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg. This recall was initiated because an individual bottle of Butalbital, Acetaminophen, and Caffeine Tablets USP, 50mg/325mg/40mg, 500 count was found incorrectly labeled with a Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg/500mg, 1000 count label, printed with Lot Number C0590909B. Lots C0390909A, C0400909A, C0410909A used the same stock inventory of labels as Lot C0590909B and are potentially impacted.

Because the recalled bottles may contain incorrect tablets, patients may unintentionally take butalbital and caffeine instead of hydrocodone (Acetaminophen is in both preparations.) Unintentional administration of butalbital could result in symptoms such as sedation, lightheadedness, dizziness, and nausea. Additionally, patients with an allergy to butalbital could experience a hypersensitivity reaction. Side effects due to caffeine are less likely, due to the small amounts in this formulation, however, those individuals with a sensitivity to caffeine may experience symptoms such as tremors, irritability, and difficulty sleeping. Patients who were receiving hydrocodone for chronic pain might experience worsening pain and withdrawal symptoms as a result of this substitution. No injuries have been reported to date.

The recall includes the following products:

- Butalbital, Acetaminophen, and Caffeine Tablets, USP, 50mg/325mg/40mg, NDC 0603-2544-28 500 count, Lot Numbers C0390909A, C0400909A, C0410909A, C0590909B
- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5mg / 500mg, NDC 0603-3882-32, 1000 count, Lot Numbers C0390909A, C0400909A, C0410909A, C0590909B

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

These lots were distributed between November 13, 2009 and April 9, 2010 to wholesale and retail pharmacies nationwide (including Puerto Rico). Lot numbers can be found on the side of the manufacturer's bottle. Butalbital, Acetaminophen, and Caffeine Tablets are (approximately 11.0 mm in diameter), white round-shaped tablets, debossed (2544) on one side, and debossed (V) on the reverse side; Hydrocodone Bitartrate and Acetaminophen Tablets are (approximately 16.5 mm in length), white with green specs, round, capsule shaped, scored tablets, debossed (3594) and (V) on one side and plain on the reverse side. All patients who have filled prescriptions of Hydrocodone Bitartrate and Acetaminophen manufactured by Qualitest, are asked to double check the identity of their tablets.

Tablet descriptions:

Hydrocodone Bitartrate and Acetaminophen Tablets, USP 7.5 mg/500 mg are supplied as white with green specks, capsule-shaped, scored tablets, debossed "3594" on one side and debossed "V" on the reverse side.

Butalbital, Acetaminophen and Caffeine Tablets, USP

Containing 50 mg butalbital, 325 mg acetaminophen and 40 mg caffeine. Available as white, round shaped tablets, debossed "2355" on one side, and debossed "V" on the reverse side.

Qualitest is notifying all customers who may have received affected product and arranging for the return of any affected product.

Consumers and patients with questions may contact Qualitest at 1-800-444-4011 for more information. Monday through Friday between the hours of 8AM and 5PM CST.

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

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

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 8AM and 5PM CST.

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 Pharmaceuticals (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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[RSS Feed for FDA Recalls Information](#)⁴ [what's this?]⁵

Photo: [Product Labels](#)⁶