



Mitchell E. Daniels, Jr.
Governor

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

DATE: February 7, 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; Hydrocodone Bitartrate and Acetaminophen Tablets was found incorrectly labeled with a Phenobarbital Tablets; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. These lots were distributed between Sept. 21, 2010 and Dec. 29, 2010 to wholesale and retail pharmacies nationwide (including Puerto Rico). Detail information is not available at this time. In addition, if any recalled products are 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 Recall Of Hydrocodone Bitartrate And Acetaminophen Tablets, USP 10 MG / 500 MG, NDC 0603-3888-20, 60 Count, Lot Numbers T150G10B, T120J10E And T023M10A And Phenobarbital Tablets, USP 32.4 MG, NDC 0603-5166-32, 1000 Count, Lot Numbers T150G10B, T120J10E And T023M10A

Contact:
Consumers
800-444-4011

Media
Kevin Wiggins
610-459-7281

Investors/Media
Blaine Davis
610-459-7158

FOR IMMEDIATE RELEASE - February 5, 2011 - Qualitest Pharmaceuticals today issued a voluntary nationwide recall of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg / 500mg, NDC 0603-3888-20, 60 count, Lot Numbers T150G10B, T120J10E and T023M10A, and Phenobarbital Tablets, USP 32.4 mg, NDC 0603-5166-32, 1000 count, Lot Numbers T150G10B, T120J10E and T023M10A. An individual bottle of Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg / 500mg, NDC 0603-3888-20, 60 count was found incorrectly labeled with a Phenobarbital Tablets, USP 32.4 mg, NDC 0603-5166-32, 1000 count label, printed with Lot Number T150G10B. Lots T120J10E and T023M10A used the same stock inventory of labels as Lot T150G10B and are potentially impacted.

As a result of this mix-up patients may unintentionally take Hydrocodone and acetaminophen tablets, instead of the intended dose of Phenobarbital. Unintentional administration of Hydrocodone can lead to serious adverse events including respiratory depression, CNS depression, coma and death, especially in opioid naïve patients and patients on other CNS depressants. Unintentional administration of acetaminophen may result in liver toxicity in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day. Additionally, missing doses of Phenobarbital could result in loss of seizure control.

No injuries have been reported to date.

Consumers who have affected product should stop using the product and contact Qualitest at 1-800-444-4011 for reimbursement. The lot number can be found on the side of the bottle.

The recall includes the following products:

- Hydrocodone Bitartrate and Acetaminophen Tablets, USP 10mg / 500mg, NDC 0603-3888-20, 60 count, Lot Numbers T150G10B, T120J10E and T023M10A
- Phenobarbital Tablets, USP 32.4 mg, NDC 0603-5166-32, 1000 count, Lot Numbers T150G10B, T120J10E and T023M10A

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

These lots were distributed between Sept. 21, 2010 and Dec. 29, 2010 to wholesale and retail pharmacies nationwide (including Puerto Rico). Lot numbers can be found on the side of the bottle. Hydrocodone Bitartrate and Acetaminophen Tablets are large (approximately 16.5 mm in length), pink, capsule-shaped tablets, debossed (3600) on one side, and debossed (V) on the reverse side; Phenobarbital Tablets are small (approximately 6.4 mm in diameter), white, round, biconvex, scored tablets, debossed (5012) and (V) on one side and plain on the reverse side. All patients who have filled prescriptions of Phenobarbital manufactured by Qualitest, are asked to double check the identity of their tablets.

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

Consumers with questions may contact Qualitest at 1-800-444-4011 for more information.

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.

- Telephone: 1-800-444-4011
- Online: <http://www.fda.gov/MedWatch/report.htm>⁹
- Regular Mail: Use postage-paid FDA form 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>¹⁰ Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

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.com¹¹).

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[RSS Feed for FDA Recalls Information](#)¹² [what's this?¹³]

[Photo: Product Labels](#)¹⁴