



**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 16, 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; Multiple lots of oral contraceptives because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible; 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. Qualitest Pharmaceuticals today issued a voluntary, nationwide, retail-level recall of multiple lots of oral contraceptives. 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 a Nationwide Voluntary Recall of Oral Contraceptives

Contact:
Consumer:
1-877-300-6153

Media:
Kevin Wiggins
(610) 459-7281

FOR IMMEDIATE RELEASE - September 15, 2011 - Qualitest Pharmaceuticals today issued a voluntary, nationwide, retail-level recall of multiple lots of oral contraceptives. The recall is being implemented because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date no longer visible. This packaging error and the potential for this error to have affected other oral contraceptive products resulted in the company issuing the recall of multiple lots.

As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. These packaging defects do not pose any immediate health risks. However, consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately and consult their health care provider or pharmacist. Pharmacies are being instructed to contact consumers who have received affected product.

Qualitest is dedicated to ensuring the safe and effective use of its products, including oral contraceptives. The source of the error is currently under investigation and the company is committed to rectifying the issue in a timely manner.

The recall is effective immediately and includes the following products:

- Cyclafem™ 7/7/7
- Cyclafem™ 1/35
- Emoquette™
- Gildess® FE 1.5/30
- Gildess® FE 1/20
- Orsythia™
- Previfem®
- Tri-Previfem®

The affected lot numbers can be found at the following URL:
<http://www.qualitestrx.com/pdf/OCRecall.pdf>¹

Doctors, pharmacists or women seeking additional information on this recall, or consumers who have affected products, should contact Qualitest toll free at 1-877-300-6153 between the hours of 8:00 a.m. and 5:00 p.m. CT Monday through Friday for information or to arrange return of any affected product. The lot numbers can be found on the bottom of the box or the individual blister card.

Adverse reactions or quality problems experienced with the use of these products may be reported to Qualitest toll free at 1-877-300-6153 or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Online: www.fda.gov/medwatch/report.htm²

Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at:
www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
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, specialty generics and medical devices and services.
(www.endo.com)³.

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