

Administrator

From: TPA Communications [communications@tnpharm.org]

Sent: Monday, September 26, 2011 2:09 PM

To: broadcast@tnpharm.org

Subject: Oral Contraceptives Recalled

To: 2011 & 2012 TPA Members

TPA has received news of the following nationwide, retail-level recall of multiple lots of oral contraceptives, issued by Qualitest Pharmaceuticals on September 15.

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:

- Cyclofem™ 7/7/7
- Cyclofem™ 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>

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.htm

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

To help you stay informed of important developments, the Tennessee Pharmacists Association is pleased to provide you with legislative, healthcare-related, regulatory and other notices as a benefit of membership.

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