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:** January 7, 2011

**TO:** All Local Health Departments
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

**SUBJECT:** Teva Pharmaceuticals, U.S.A Recall

**SUGGESTED ACTION:** **Unclassified Recall; Metronidazole Tablets USP, 250mg, lot 312566, expiration date 05/2012. This product lot is being recalled due to the presence of underweight tablets; Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. The affected Metronidazole lot is packaged in 250 count bottles and was distributed nationwide to wholesalers and retailers. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.**

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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.

### Teva Pharmaceuticals, U.S.A issues a voluntary nationwide recall of Metronidazole Tablets USP, 250mg Due to Low Weight Tablets

**Contact:**
Consumer Contact
866-262-1243

Media Contact
Denise Bradley
215-591-8974

**FOR IMMEDIATE RELEASE** - January 6, 2011 - Teva Pharmaceuticals, U.S.A, is voluntarily recalling Metronidazole Tablets USP, 250mg, lot 312566, expiration date 05/2012. This product lot is being recalled due to the presence of underweight tablets.

Underweight tablets may not contain the full amount of active ingredient within a single tablet, a consumer may not receive the prescribed dose. This may cause the infection the drug was intended to treat to worsen or recur, which could be life-threatening when treating severe infections. To date, Teva Pharmaceuticals, U.S.A. has not received any adverse events associated with the use of this product lot.

Metronidazole is indicated for the treatment of symptomatic and asymptomatic trichomoniasis, and treatment of asymptomatic consorts, amebiasis and a variety of anaerobic bacterial infections. The affected Metronidazole lot is packaged in 250 count bottles and was distributed nationwide to wholesalers and retailers.

Wholesalers and retailers have been previously notified of this recall via overnight notification on 10/25/10 and are in the process of returning this product lot. Consumers who have lot 312566 in their possession are instructed to cease using the product and return it to their pharmacy. Wholesalers and retailers should cease distribution and examine their inventory immediately.

Adverse events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- **Online**:http://www.fda.gov/MedWatch/report.htm[9]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[10] Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

Consumers with questions regarding this recall may contact 866-262-1243 from 9:00am – 5:00pm ET Monday –Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product. Teva Pharmaceuticals, U.S.A is voluntarily recalling the aforementioned product lot with the knowledge of the U.S. Food and Drug Administration.

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