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: March 28, 2011

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

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

SUBJECT: Greenstone LLC Recall

SUGGESTED ACTION: **Unclassified Recall; Citalopram 10mg Tablets (100-count bottle) and Finasteride 5mg Tablets (90-count bottle) due to the possibility that incorrect labels have been placed on the bottles by a third-party manufacturer; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. The recalled products were distributed nationwide in retail stores. 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.

Greenstone Announces Voluntary Nationwide Recall Of Citalopram And Finasteride Due to Possible Mislabeling

Contact:
Pfizer Inc.
1-800-438-1985

FOR IMMEDIATE RELEASE - March 26, 2011 - Greenstone LLC announced today that it is voluntarily conducting a recall, to the patient level, of medicines with lot number FI0510058-A on the label. This includes Citalopram 10mg Tablets (100-count bottle) and Finasteride 5mg Tablets (90-count bottle), both distributed in the U.S. market. The recall is due to the possibility that incorrect labels have been placed on the bottles by a third-party manufacturer. This is the only lot number being recalled and no other lots or markets are believed to be impacted.

Importantly, bottles labeled as Citalopram Lot # FI0510058-A may contain Finasteride. Patients who believe they may have ingested the wrong medication should contact their physician as soon as possible. Women who are, or may become pregnant, should not take or handle Finasteride due to the possible risk of side effects which may cause abnormalities to the external genitalia of a developing male fetus. Citalopram is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or pimozide, It is also contraindicated in patients with a hypersensitivity to Citalopram or any of the inactive ingredients in the tablet. Patients who discontinue Citalopram abruptly by inadvertently taking the mislabeled product may experience discontinuation symptoms and/or worsening of depression.

Bottles of either Citalopram (used to treat depression) or Finasteride (for the treatment of benign prostatic hyperplasia) with lot number FI050058-A should be returned to the pharmacist.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. Also, any adverse events that may be related to the use of these products should be reported to Pfizer Inc. at-1-800-438-1985 (24 hours a day) or to FDA's Med Watch Program either online, by regular mail or by fax.

- **Online**:www.fda.gov/medwatch/report.htm[11]
- **Regular Mail**: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[22]. Mail to the address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

Greenstone LLC is a wholly owned subsidiary of Pfizer Inc.

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