Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: September 14, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Medistat RX, LLC – RECALL [Drug]

AFFECTED PRODUCT: **All non-expired drug products produced for sterile use distributed by Medistat RX, LLC.**

SUMMARY: **Unclassified Recall; The recall is due to possible contamination. The FDA observed significant deficiencies that raise concerns about Medistat's ability to assure the sterility of drug products that it produced.**

The recalled products were distributed between November 1, 2014, and September 3, 2015.

The products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Patients who have received any drug products produced by Medistat and have concerns should contact their health care professional. FDA encourages health care professionals and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program. The FDA will continue to work closely with the Alabama Board of Pharmacy to protect the public health.**

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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.

FDA Announces Medistat RX's Nationwide Voluntary Recall of Sterile Drug Products

FOR IMMEDIATE RELEASE – September 9, 2015 – Foley, AL – The U.S. Food and Drug Administration is alerting health care professionals and patients of a voluntary recall of all non-expired drug products produced for sterile use and distributed nationwide by Medistat RX, LLC, in Foley, Alabama, due to possible contamination. The recalled products were distributed between November 1, 2014, and September 3, 2015.

Contaminated drugs put patients at risk of serious infection. Health care professionals should immediately check their medical supplies, quarantine any drug products marketed as sterile from Medistat, and not administer them to patients. Administration of a non-sterile drug product intended to be sterile may result in serious and potentially life-threatening infections or death.

During an ongoing inspection, FDA investigators and Alabama state inspectors observed significant deficiencies that raise concerns about Medistat's ability to assure the sterility of drug products that it produced. Medistat voluntarily ceased sterile compounding operations on September 1, 2015.

FDA has received reports of several adverse events that are potentially associated with drug products made by Medistat. Patients who have received any drug products produced by Medistat and have concerns should contact their health care professional. FDA encourages health care professionals and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA will continue to work closely with the Alabama Board of Pharmacy to protect the public health.

FDA previously inspected Medistat in September 2014 and issued a Form FDA 483. Medistat is registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) as an outsourcing facility. The Drug Quality and Security Act, signed into law on November 27, 2013, added a new section 503B to the FDCA. Under section 503B, a compounder can elect to become an outsourcing facility. Outsourcing facilities:

- Must comply with current good manufacturing practice requirements;
- Will be subject to inspection by FDA according to a risk-based schedule; and
- Must meet certain other requirements, such as reporting adverse events and providing FDA with certain information about the products they compound.

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