Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: May 6, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Teva Parenteral Medicines – RECALL [Drug]

AFFECTED PRODUCT: Adrucil® (fluorouracil injection, USP) 5 g/100 mL (50 mg/mL)

SUMMARY: Unclassified Recall; The recall is due to the potential presence of particulate matter identified as aggregate of silicone rubber pieces from a filler diaphragm and fluorouracil crystals.

The recalled lots are as follows:

Lot #	Exp. Date	Vial Size	NDC# individual	NDC# carton of 5
31317858B	11/2015	100 mL	0703-3019-11	0703-3019-12
31317899B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317906B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317958B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317959B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318103B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318137B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318533B	7/2016	100 mL	0703-3019-11	0703-3019-12

Adrucil® 5 g/100 ml vials were distributed in the United States. Teva has distributed this product through the normal distribution chain of wholesalers, retailers, and pharmacies.

SUGGESTED ACTION: For consumer inquiry only. For medical related questions please contact Medical Information at 888-838-2872, option 3, then option 4. If a customer service related question, please contact Teva Customer Service at 800-545-8800 Monday – Friday; 8:00 – 5:00 EST.

****

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 Parenteral Medicines Initiates Voluntary Nationwide Recall of Select Lots of Adrucil® (fluorouracil Injection, USP) 5 g/100 mL (50 mg/mL) Due to Particulate Matter

Contact:
Media:
Denise Bradley
215-591-8974
denise.bradley@tevapharm.com

FOR IMMEDIATE RELEASE — May 4th 2015 — Teva Parenteral Medicines today announced a voluntary recall of eight lots of Adrucil® (fluorouracil injection, USP) 5 g/100 mL (50 mg/mL) due to the potential presence of particulate matter identified as aggregate of silicone rubber pieces from a filler diaphragm and fluorouracil crystals. The recalled lots are as follows:

Lot #	Exp. Date	Vial Size	NDC# individual	NDC# carton of 5
31317858B	11/2015	100 mL	0703-3019-11	0703-3019-12
31317899B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317906B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317958B	12/2015	100 mL	0703-3019-11	0703-3019-12
31317959B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318103B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318137B	12/2015	100 mL	0703-3019-11	0703-3019-12
31318533B	7/2016	100 mL	0703-3019-11	0703-3019-12

Administration of an intravenous product with particulate matter has the potential to result in inflammation, allergic reactions, or blockage of blood vessels, leading to tissue death, which may be life-threatening if vital organs are affected. To date, Teva has not received any reports of adverse events related to this recall.

Adrucil® Injection is used in the palliative management of carcinoma of the colon, rectum, breast, stomach and pancreas and is packaged in pharmacy bulk packages. The pharmacy bulk package has five 5 g/100ml vials per shelf pack. Individual Adrucil® 5 g/100 ml vials have the NDC code 0703-3019-11 and the pharmacy shelf pack has the NDC code 0703-3019-12. The Adrucil® 5 g/100 ml vial can be further identified by the statement on the label in red that states "PHARMACY BULK PACKAGE NOT FOR DIRECT INFUSION". Adrucil® 5 g/100 ml vials were distributed in the United States. Teva has distributed this product through the normal distribution chain of wholesalers, retailers, and pharmacies.

Teva has notified its direct customers by mail and has issued an Urgent Drug Recall Letter to direct customers. Teva is arranging for impacted product to be returned to Inmar. Anyone with an existing inventory of the recalled lots should stop use and distribution, and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the user level.

For medical related questions please contact Medical Information at 888-838-2872, option 3, then option 4. If a customer service related question, please contact Teva Customer Service at 800-545-8800 Monday – Friday; 8:00 – 5:00 EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product. Teva Parenteral Medicines is voluntarily recalling the aforementioned product lots with the knowledge of the U.S. Food and Drug Administration.

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
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm
- Mail to address on the pre-addressed form.

- Fax: 1-800-FDA-0178

Teva Parenteral Medicines Initiates Voluntary Nationwide Recall of Select Lots of Adrucil® (fluorouracil Injection, USP) 5 g/100 mL (50 mg/mL) Due to Particulate Matter

Photo