Teva Pharmaceuticals, USA Inc.

URGENT DRUG RECALL – RETAIL LEVEL – INITIATED 4/28/15

ADRUCIL® (fluorouracil injection, USP), 5g/100mL (50mg/mL)

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Vial Size	NDC# individual vials	NDC# carton of 5 vials
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

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **ADRUCIL® (fluorouracil injection, USP), 5g/100mL (50mg/mL)** distributed under the **Teva Parenteral Medicines, Inc. label.** This recall is being carried out to the **RETAIL LEVEL** due to the presence of particulate matter identified as silicone rubber from the filler diaphragm. The use of or exposure to the product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **ADRUCIL® (fluorouracil injection, USP), 5g/100mL (50mg/mL).**
- Our records indicate we shipped this product between July 28, 2014 and April 3, 2015.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: recallnotice@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800. For medical-related questions please contact Medical Information at 888-838-2872, option 3, then, option 4. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

James D. Young

James S. Young
Director, Quality Systems & Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals, USA Inc.

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STOCK RESPONSE FORM

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Lot #	Exp. Date	Vial Size	Quantity to Return # of single vials NDC# 0703-3019-11	Quantity to Return # of cartons of 5 vials NDC# 0703-3019-12
31317858B	11/2015	100 mL		
31317899B	12/2015	100 mL		
31317906B	12/2015	100 mL		
31317958B	12/2015	100 mL		
31317959B	12/2015	100 mL		
31318103B	12/2015	100 mL		
31318137B	12/2015	100 mL		
31318533B	7/2016	100 mL		

I have checked my stock and:

____ I **do not** have stock of the recalled item(s) **OR** ____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800

Medical-related questions - contact Medical Information 888-838-2872, option 3, then, option 4.

Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

Inmar/MedTurn Use Only:				
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