Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 10/11/13

Daunorubicin Hydrochloride Injection 20 mg/4 mL (5 mg/mL)

MANUFACTURED BY:
Teva Parenteral Medicines, Inc.
Irvine, CA 92618

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

Lot #	Exp Date	NDC# Carton of 10 vials	NDC# Individual 4 mL vials
31314801B	2/2014	0703-5233-13	0703-5233-11
31314990B	2/2014	0703-5233-13	0703-5233-11
31314991B	2/2014	0703-5233-13	0703-5233-11
31315014B	2/2014	0703-5233-13	0703-5233-11
31315155B	6/2014	0703-5233-13	0703-5233-11
31315279B	6/2014	0703-5233-13	0703-5233-11
31315837B	10/2014	0703-5233-13	0703-5233-11
31315921B	10/2014	0703-5233-13	0703-5233-11
31316029D	12/2014	0703-5233-13	0703-5233-11
31316029C	12/2014	0703-5233-93	0703-5233-91

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Daunorubicin Hydrochloride Injection 20 mg/4 mL (5 mg/mL)** distributed under the **Teva Pharmaceuticals and Novation's NovaPlus® labels**. This recall is being carried out to the **RETAIL LEVEL** due to the potential for the presence of particulate matter. The probability of adverse health effects are expected to be low.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Daunorubicin Hydrochloride Injection 20 mg/4 mL (5 mg/mL).**
- Our records indicate we shipped this product between March 21, 2012 and July 22, 2013.
- 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 Affairs at 888-838-2872, option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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Daunorubicin Hydrochloride Injection 20 mg/4 mL (5 mg/mL)

STOCK RESPONE 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	Quantity to Return NDC 0703-5233-13 # Carton of 10 vials	Quantity to Return NDC 0703-5233-11 # Individual 4 mL vials
31314801B	2/2014		
31314990B	2/2014		
31314991B	2/2014		
31315014B	2/2014		
31315155B	6/2014		
31315279B	6/2014		
31315837B	10/2014		
31315921B	10/2014		
31316029D	12/2014		
Lot #	**Exp Date**	**Quantity to Return NDC 0703-5233-93 # Carton of 10 vials**	**Quantity to Return NDC 0703-5233-91 # Individual 4 mL vials**
31316029C	12/2014		

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 Services at 800-545-8800

Medical related questions - contact Medical Affairs 888-838-2872, option 9

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

Inmar/MedTurn Use Only:				
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