Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL – 10/24/2013

Copaxone® (glatiramer acetate injection), 20mg/mL

MANUFACTURED BY:
IVAX Pharmaceuticals UK
Runcorn, Cheshire, United Kingdom

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

Lot #	Exp Date	Size	NDC # (single syringes or carton of 30)
X06381	10/2014	1mL	68546-317-30

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lot of **Copaxone® (glatiramer acetate injection)** distributed under the **Teva Neuroscience, Inc. label.** This recall is being carried out to the **RETAIL LEVEL** due to the presence of a single foreign particle identified from a customer complaint in one (1) prefilled syringe. No adverse health effects are expected.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Copaxone® (glatiramer acetate injection).**
- Our records indicate we shipped this product between April 9, 2013 and May 22, 2013.
- Immediately discontinue distribution of the specific lot 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 Services at 800-545-8800. For medical-related questions please contact Medical Information at 888-483-8279 (888-4TEVA-RX). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 select option 1 then option 3 or acquire it from clsnetlink.com.

Sincerely,

Jon Hyde FOR CHRISTOPHER MURDOCK

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

Teva Pharmaceuticals USA, Inc.

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<u>STOCK RESPONSE FORM</u>

Copaxone® (glatiramer acetate injection), 20mg/mL

<u>Please fill out completely</u>   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	Size	# of single syringes NDC # 68546-317-30	# of cartons (count of 30) NDC# 68546-317-30
X06381	10/2014	1mL		

<u>I have checked my stock and:</u>

_____ 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: _____

<u>Inquiries regarding this recall are to be directed to the following:</u>

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 Information 888-483-8279 (888-4TEVA-RX)

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

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B