Teva Pharmaceuticals USA, Inc.

*Amended to Retail Level

URGENT DRUG RECALL – RETAIL LEVEL – Amended 4/10/2013

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

MANUFACTURED BY:
Teva Pharmaceutical Industries, Ltd.
Kfar Saba, Israel

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

Lot #	Exp Date	Size	NDC # (single syringes or carton of 30)
P53847	01/2014	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 receiving an elevated number of patient complaints related to a visible presence of medical grade silicone oil essential to the functionality of the syringe and plunger stopper system.

While not reported, the use of this product may potentially put patients at risk for injection site reactions. In addition, impaired wound healing, skin breakdown, or immunogenicity which could lead to reduced drug effectiveness and/or more serious side effects cannot be excluded. This recall was originally initiated on December 5, 2012 to the wholesale level.

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 August 27, 2012 and September 6, 2012.
- 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 913-451-6354. 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,

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

Teva Pharmaceuticals USA, Inc.

*Amended to Retail Level

URGENT DRUG RECALL – RETAIL LEVEL – Amended 4/10/2013

STOCK RESPONSE FORM

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

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	Size	# of single syringes NDC # 68546-317-30	# of cartons (count of 30) NDC# 68546-317-30
P53847	01/2014	1mL		

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 Information 913-451-6354

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

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B