Goldline Laboratories, Inc. (Teva Pharmaceuticals USA, Inc.)

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 12/18/13

Hydralazine Hydrochloride Tablets USP, 25 mg and 50 mg

MANUFACTURED BY:
Pliva Krakow Pharmaceutical Company S.A., Krakow, Poland/
Teva Czech Industries s.r.o. Opava-Komarov, Czech Republic

DISTRIBUTED BY:
Goldline Laboratories, Inc.
Sellersville, PA 18960

Lot #	Label*	Exp. Date	Strength	Single Blister	Carton Containing 100 (10 x 10) Unit Dose Tablets
14071112AA	1	3/2014	25 mg	0182-0554-00	0182-0554-89
14071112AB	1	3/2014	25 mg	0182-0554-00	0182-0554-89
14071012BA	1	3/2014	25 mg	0182-0554-00	0182-0554-89
14071012BB	1	3/2014	25 mg	0182-0554-00	0182-0554-89
6A201018VA	2	1/2014	50 mg	0182-0555-00	0182-0555-89

*1 - Manufactured By: Pliva Krakow Pharmaceutical Company S.A., Krakow, Poland
*2 - Manufactured By: Teva Czech Industries s.r.o. Opava-Komarov, Czech Republic

Dear Customer:

Teva Pharmaceuticals USA, Inc., on behalf of Goldline Laboratories, Inc. (Goldline Laboratories, Inc. is an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.) is voluntarily recalling the above lots of **Hydralazine Hydrochloride Tablets USP, 25 mg and 50 mg** distributed under the **Goldline Laboratories label**. This recall is being carried out to the **RETAIL LEVEL** due to the potential for tablets to be out of specification for impurities throughout shelf life. The exposure to this product may cause medically reversible adverse health consequences and the probability of serious adverse health consequences is remote.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Hydralazine Hydrochloride Tablets USP, 25 mg and 50 mg.**
- Our records indicate we shipped this product between November 15, 2012 and January 17, 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.

Goldline Laboratories, Inc. (Teva Pharmaceuticals USA, Inc.)

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Hydralazine Hydrochloride Tablets USP, 25 mg and 50 mg

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	Strength	# of Single Blister NDC# 0182-0554-00	# of Cart Carton Containing 100 (10 x 10) Unit Dose Tablets NDC# 0182-0554-89
14071112AA	3/2014	25 mg		
14071112AB	3/2014	25 mg		
14071012BA	3/2014	25 mg		
14071012BB	3/2014	25 mg		

Lot #	Exp. Date	Strength	# of Single Blister NDC# 0182-0555-00	# of Carton Containing 100 (10 x 10) Unit Dose Tablets NDC# 0182-0555-89
6A201018VA	1/2014	50 mg		

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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