CARACO
PHARMACEUTICAL LABORATORIES, LTD.

URGENT DRUG RECALL
VENLAFAXINE HCl ER 150 MG TABLETS

June 12, 2014

Dear Trading Partner,

This notice is to inform you of a drug product recall involving

Drug Product Name: Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg

Manufacturer: Sun Pharmaceutical Industries, Ltd

NDC Number: 41616-758-83 (30 CRC) and 41616-758-81 (90 CRC).

Dosage Form: Extended Release Tablet

Route of Administration: Oral

Type of Drug Product: Prescription

Intended Use/ Indications: Indicated for the treatment of major depressive disorder.

Package Type and Number of Doses/Sizes: 30 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC) and 90 tablets packed in HDPE bottles closed with Child Resistant Caps (CRC).

Batch Numbers dispatched to Caraco:

Product name	Pack Size	Batch No.	Mfg. Date	Exp. Date
Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg	30 count CRC pack	JKL5054A	09/2012	08/2014
	90 count CRC pack	JKL5054B	09/2012	08/2014
	30 count CRC pack	JKM2305A	04/2013	03/2015
	90 count CRC pack	JKM2305B	04/2013	03/2015

Reason for Recall
This recall is voluntarily initiated based upon stability results. The product may not meet the drug release specification throughout it expiry period. As a precaution, Caraco is voluntarily recalling these batches ((Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg; batch # JKL5054A, JKL5054B, JKM2305A and JKM2305B).

Immediately examine your inventory and quarantine lot subject to this recall. Please stop distributing these lots immediately. This recall has been classified as **a retail level recall (Class II).** In addition, if you have further distributed this product, please notify them at once of this product recall. Your notification to you customers may be enhanced by including a copy of this recall letter.

This recall is being made with the knowledge of the Food and Drug Administration.
For return of affected product, please email recallnotice@inmar.com or call 800-967-5952. Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

If there are any further questions, please feel free to contact me at 800-818-4555 x 4105.

Sincerely,

Robert Kurkiewicz
Sr. Vice President, Regulatory

CARACO
PHARMACEUTICAL LABORATORIES, LTD.

URGENT: DRUG RECALL – RESPONSE FORM

Please Complete Form and Fax to: 817-868-5362

or Email to: recallnotice@inmar.com

We do not have any stock ☐

Or,

Please enter the quantity you shall be returning to Inmar

Product name	Pack Size	Lot Number	Mfg. Date	Exp. Date	Quantity Being Returned to Inmar
Venlafaxine Hydrochloride Extended-Release Tablets, 150 mg	30 count CRC pack	JKL5054A	09/2012	08/2014	
	90 count CRC pack	JKL5054B	09/2012	08/2014	
	30 count CRC pack	JKM2305A	04/2013	03/2015	
	90 count CRC pack	JKM2305B	04/2013	03/2015	

Name_____ DEA#_____

Company_____

Address_____

City _____State _____ Zip Code_____

Phone Number_____ Email_____

Wholesaler_____City/State_____

For return of affected product, please email recallnotice@inmar.com or call 800-967-5952