Zydus Pharmaceuticals (USA) Inc.
73 Route 31 North • Pennington, NJ 08534
Phone: 609-730-1900
Fax: 609-730-1998

Dated: July 19th, 2016

URGENT DRUG RECALL

Dear Customer:

This official communication is to notify you that Zydus Pharmaceuticals USA Inc., is voluntarily recalling the below mentioned drug product at the **RETAIL LEVEL**:

Sr. No.	Product Name	Lot No.	Expiry	Pack Size	NDC No.	Distribution Start Date	Distribution End Date
1	Venlafaxine HCL ER Capsule USP 150mg	MR10518	09/2017	30	68382-036-06	17-Dec-15	17-Dec-15
2	Venlafaxine HCL ER Capsule USP 150mg	MR10197	09/2017	90	68382-036-16	17-Dec-15	4-Jan-16
3	Venlafaxine HCL ER Capsule USP 150mg	MR10195	09/2017	90	68382-036-16	7-Dec-15	15-Dec-15
4	Venlafaxine HCL ER Capsule USP 150mg	MR10404	09/2017	1000	68382-036-10	15-Dec-15	15-Dec-15
5	Venlafaxine HCL ER Capsule USP 150mg	MR10406	09/2017	1000	68382-036-10	8-Dec-15	8-Dec-15
6	Venlafaxine HCL ER Capsule USP 150mg	MR10521	09/2017	1000	68382-036-10	16-Dec-15	18-Dec-15
7	Venlafaxine HCL ER Capsule USP 150mg	MR10744	10/2017	1000	68382-036-10	13-Jan-16	21-Jan-16
8	Venlafaxine HCL ER Capsule USP 150mg	MR11051	10/2017	30	68382-036-06	12-Jan-16	20-Jan-16
9	Venlafaxine HCL ER Capsule USP 150mg	MR11052	10/2017	30	68382-036-06	19-Jan-16	2-Feb-16
10	Venlafaxine HCL ER Capsule USP 150mg	MR11482	10/2017	90	68382-036-16	19-Jan-16	26-Jan-16
11	Venlafaxine HCL ER Capsule USP 150mg	MR11053	10/2017	30	68382-036-06	2-Feb-16	2-Feb-16
12	Venlafaxine HCL ER Capsule USP 150mg	MR11054	10/2017	30	68382-036-06	2-Feb-16	2-Feb-16
13	Venlafaxine HCL ER Capsule USP 150mg	MR11055	10/2017	1000	68382-036-10	30-Dec-15	21-Jan-16
14	Venlafaxine HCL ER Capsule USP 150mg	MR11228	10/2017	1000	68382-036-10	30-Dec-15	30-Dec-15
15	Venlafaxine HCL ER Capsule USP 150mg	MR11287	10/2017	1000	68382-036-10	20-Jan-16	1-Feb-16
16	Venlafaxine HCL ER Capsule USP 150mg	MR11285	10/2017	1000	68382-036-10	21-Jan-16	21-Jan-16
17	Venlafaxine HCL ER Capsule USP 150mg	MR11288	10/2017	1000	68382-036-10	1-Feb-16	8-Mar-16
18	Venlafaxine HCL ER Capsule USP 150mg	MR11289	10/2017	1000	68382-036-10	19-Feb-16	19-Feb-16
19	Venlafaxine HCL ER Capsule USP 150mg	MR11286	10/2017	1000	68382-036-10	21-Jan-16	21-Jan-16

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Sr. No.	Product Name	Lot No.	Expiry	Pack Size	NDC No.	Distribution Start Date	Distribution End Date
20	Venlafaxine HCL ER Capsule USP 150mg	MR11403	11/2017	30	68382-036-06	2-Feb-16	2-Feb-16
21	Venlafaxine HCL ER Capsule USP 150mg	MR11479	11/2017	90	68382-036-16	12-Jan-16	14-Jan-16
22	Venlafaxine HCL ER Capsule USP 150mg	MR11480	11/2017	90	68382-036-16	13-Jan-16	1-Feb-16
23	Venlafaxine HCL ER Capsule USP 150mg	MR11481	11/2017	90	68382-036-16	1-Feb-16	2-Feb-16
24	Venlafaxine HCL ER Capsule USP 150mg	MR11483	11/2017	90	68382-036-16	2-Feb-16	16-Feb-16
25	Venlafaxine HCL ER Capsule USP 150mg	MR11567	11/2017	1000	68382-036-10	19-Feb-16	19-Feb-16
26	Venlafaxine HCL ER Capsule USP 150mg	MR11665	11/2017	90	68382-036-16	17-Mar-16	24-Mar-16
27	Venlafaxine HCL ER Capsule USP 75mg	MR11150	10/2017	1000	68382-035-10	23-Feb-16	23-Feb-16
28	Venlafaxine HCL ER Capsule USP 75mg	MR11151	10/2017	1000	68382-035-10	23-Feb-16	23-Feb-16
29	Venlafaxine HCL ER Capsule USP 75mg	MR11854	10/2017	1000	68382-035-10	1-Mar-16	25-Apr-16
30	Venlafaxine HCL ER Capsule USP 75mg	MR11798	11/2017	1000	68382-035-10	28-Apr-16	28-Apr-16
31	Venlafaxine HCL ER Capsule USP 75mg	MR11799	11/2017	1000	68382-035-10	28-Apr-16	28-Apr-16
32	Venlafaxine HCL ER Capsule USP 75mg	MS1214	11/2017	1000	68382-035-10	9-May-16	23-May-16
33	Venlafaxine HCL ER Capsule USP 75mg	MS1215	12/2017	90	68382-035-16	4-May-16	5-May-16
34	Venlafaxine HCL ER Capsule USP 75mg	MS1217	12/2017	30	68382-035-06	29-Feb-16	3-May-16
35	Venlafaxine HCL ER Capsule USP 75mg	MS1218	12/2017	30	68382-035-06	2-May-16	4-May-16

Zydus Pharmaceuticals USA Inc. has decided to initiate a voluntary recall of the above drug product based on our findings of an out of specification dissolution result in our retained sample of Lot No.MR11481. Based upon this and our impact assessment, we have recommended a recall of the thirty-five (35) lots mentioned in above table.

Zydus Pharmaceuticals USA Inc. is advising our customers that have these designated lots of this product in stock to discontinue the use, dispensing, and distribution of the product immediately and return it to Inmar Pharmaceuticals Services as per the details furnished below.

Seeing that the above mentioned lots are meeting the final dissolution time points, the Health Hazard Evaluation (HHE) report revealed that the marginally higher dissolution rate at four (4) hour and eight (8) hour time points pose a minimal risk to the patient. Therefore, we wish to conduct recall of these lots at **Retail Level.**

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Your assistance is appreciated and necessary to prevent further product usage.

Through this communication, at our cost, we request that you please return all of the above referenced drug product and associated lots in your current inventory. To facilitate this recall, please do the following actions:

1. Examine your available stock for the presence of above referenced lots of the drug product listed within this recall.

2. If you have the any of the listed lot numbers of the drug product in your stock, please discontinue any further distribution and quarantine it immediately. The quarantined product should be returned to: Inmar Pharmaceutical Service, South Dock, 4332 Empire Rd, Fort Worth, TX 76155. Zydus will issue a credit memo based on the corresponding units within your return to Inmar.

3. Please complete the enclosed "PRODUCT RECALL RESPONSE FORM" and fax it to us at 1-817-868-5362 or email it to rxrecalls@inmar.com. Even if you do not possess any inventory of the lots being recalled, we would appreciate your cooperation and help by still filling in and returning the form to us.

4. In the case that the identified product was distributed to a customer for redistribution or packaging, please identify your customers and notify them at once of this product recall. Please include a copy of this letter with your notification to insure proper handling and return of the product.

Please complete and return the enclosed response form as soon as possible.

If you have any questions about product safety issue, then please call Zydus Pharmaceuticals Drug Safety/ Medical Affairs at 1-877-993-8779 Option# 2.

If you have any questions in regards to return logistics or any and other issue, then please call Recall Services at 1-800-967-5952.

This recall is being made with the knowledge of the Food and Drug Administration.

We apologize for any inconvenience this voluntary recall may have caused you.

Yours Sincerely,

Prashant Desai
Sr. Vice President – Technical Operations

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PRODUCT RECALL RESPONSE FORM

URGENT DRUG RECALL

Please complete the required information and fax to **1-817-868-5362**
or email to **rxrecalls@inmar.com**
To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.

Sr.No.	Product Name	Lot No.	Expiry	Pack Size	NDC No.
1	Venlafaxine HCL ER Capsule USP 150mg	MR10518	09/2017	30	68382-036-06
2	Venlafaxine HCL ER Capsule USP 150mg	MR10197	09/2017	90	68382-036-16
3	Venlafaxine HCL ER Capsule USP 150mg	MR10195	09/2017	90	68382-036-16
4	Venlafaxine HCL ER Capsule USP 150mg	MR10404	09/2017	1000	68382-036-10
5	Venlafaxine HCL ER Capsule USP 150mg	MR10406	09/2017	1000	68382-036-10
6	Venlafaxine HCL ER Capsule USP 150mg	MR10521	09/2017	1000	68382-036-10
7	Venlafaxine HCL ER Capsule USP 150mg	MR10744	10/2017	1000	68382-036-10
8	Venlafaxine HCL ER Capsule USP 150mg	MR11051	10/2017	30	68382-036-06
9	Venlafaxine HCL ER Capsule USP 150mg	MR11052	10/2017	30	68382-036-06
10	Venlafaxine HCL ER Capsule USP 150mg	MR11482	10/2017	90	68382-036-16
11	Venlafaxine HCL ER Capsule USP 150mg	MR11053	10/2017	30	68382-036-06
12	Venlafaxine HCL ER Capsule USP 150mg	MR11054	10/2017	30	68382-036-06
13	Venlafaxine HCL ER Capsule USP 150mg	MR11055	10/2017	1000	68382-036-10
14	Venlafaxine HCL ER Capsule USP 150mg	MR11228	10/2017	1000	68382-036-10
15	Venlafaxine HCL ER Capsule USP 150mg	MR11287	10/2017	1000	68382-036-10
16	Venlafaxine HCL ER Capsule USP 150mg	MR11285	10/2017	1000	68382-036-10
17	Venlafaxine HCL ER Capsule USP 150mg	MR11288	10/2017	1000	68382-036-10
18	Venlafaxine HCL ER Capsule USP 150mg	MR11289	10/2017	1000	68382-036-10
19	Venlafaxine HCL ER Capsule USP 150mg	MR11286	10/2017	1000	68382-036-10
20	Venlafaxine HCL ER Capsule USP 150mg	MR11403	11/2017	30	68382-036-06
21	Venlafaxine HCL ER Capsule USP 150mg	MR11479	11/2017	90	68382-036-16

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Sr.No.	Product Name	Lot No.	Expiry	Pack Size	NDC No.
22	Venlafaxine HCL ER Capsule USP 150mg	MR11480	11/2017	90	68382-036-16
23	Venlafaxine HCL ER Capsule USP 150mg	MR11481	11/2017	90	68382-036-16
24	Venlafaxine HCL ER Capsule USP 150mg	MR11483	11/2017	90	68382-036-16
25	Venlafaxine HCL ER Capsule USP 150mg	MR11567	11/2017	1000	68382-036-10
26	Venlafaxine HCL ER Capsule USP 150mg	MR11665	11/2017	90	68382-036-16
27	Venlafaxine HCL ER Capsule USP 75mg	MR11150	10/2017	1000	68382-035-10
28	Venlafaxine HCL ER Capsule USP 75mg	MR11151	10/2017	1000	68382-035-10
29	Venlafaxine HCL ER Capsule USP 75mg	MR11854	10/2017	1000	68382-035-10
30	Venlafaxine HCL ER Capsule USP 75mg	MR11798	11/2017	1000	68382-035-10
31	Venlafaxine HCL ER Capsule USP 75mg	MR11799	11/2017	1000	68382-035-10
32	Venlafaxine HCL ER Capsule USP 75mg	MS1214	11/2017	1000	68382-035-10
33	Venlafaxine HCL ER Capsule USP 75mg	MS1215	12/2017	90	68382-035-16
34	Venlafaxine HCL ER Capsule USP 75mg	MS1217	12/2017	30	68382-035-06
35	Venlafaxine HCL ER Capsule USP 75mg	MS1218	12/2017	30	68382-035-06

No. of Bottles Purchased : _____

No. of bottles Consumed : _____

No. of bottles in Possession : _____

No. of bottles to be returned : _____

No. of Returns kit required : _____

Please mark as applicable

__ We currently do not have any inventory of the above listed Lot/bottles

__ We are notifying our customers

__ We have identified and notified my customers that were shipped or may have been shipped this product by_____;

__ Attached is the list of customers who received/ may have received this product. Please notify my customers.

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Any adverse event associated with recalled product? ___ Yes ___ No
If yes, please explain:

_____

_____

Please check appropriate box to describe your business

___ Wholesaler/Distributor

___ Retailers

___ Grocery Corporate Headquarters

___ Repackager

___ Manufacturer

___ Pharmacy- Retail

___ Hospital/ Medical Facility

___ Hospital Pharmacies

___ Medical Laboratory

___ Other: _____

Name: _____

Title: _____

Tel Number: _____

Firm Name: _____ DEA#_____

Address: _____

City/ State: _____

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: _____ (Name, City)

Signature: _____ Date: _____