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

March 15, 2017

URGENT DRUG RECALL

Dear Customer:

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

Divalproex Sodium DR Tablets USP 500mg, 500 count, NDC: 68382-033-05

Lot Number	Expiry Date	Distribution Start Date	Distribution End Date	Lot Number	Expiry Date	Distribution Start Date	Distribution End Date
MR6187	05/17	14-Sep-15	15-Sep-15	MR8893	08/17	25-Jan-16	27-Jan-16
MR7302	06/17	11-Nov-15	17-Nov-15	MR9014	09/17	14-Mar-16	14-Mar-16
MR7768	07/17	18-Nov-15	23-Nov-15	MR10414	09/17	29-Feb-16	08-Mar-16
MR7769	07/17	20-Nov-15	30-Nov-15	MR10928	10/17	02-May-16	06-May-16
MR8247	07/17	07-Dec-15	15-Dec-15	MR11183	11/17	23-May-16	02-Jun-16
MR8887	08/17	17-Dec-15	30-Dec-15	MR11185	11/17	31-May-16	06-Jun-16
MR8892	08/17	19-Jan-16	25-Jan-16	MR11186	11/17	06-Jun-16	09-Jun-16

Divalproex Sodium DR Tablets USP 500mg, 100 count, NDC: 68382-033-01

Lot Number	Expiry Date	Distribution Start Date	Distribution End Date	Lot Number	Expiry Date	Distribution Start Date	Distribution End Date
MR8221	07/17	05-Nov-15	20-May-16	MR10260	09/17	16-Jul-16	12-Aug-16
MR8222	07/17	20-May-16	20-May-16	MR10926	10/17	16-May-16	26-Aug-16

Zydus Pharmaceuticals USA Inc. has decided to initiate a voluntary recall of the above drug product based on a failure observed during our long-term stability study point of nine months for Divalproex Sodium DR Tablets USP 500mg Lot No.: MR8221 and Lot No.: MR8247. Though the additional lots listed above did not fail long term stability, Zydus is proactively recalling those lots as well to ensure only safe and quality product is available for our customers.

Based on Health Hazard Evaluation performed by an independent consulting firm, the immediate risk to the patient population is considered moderate. Therefore, we wish to conduct this recall at **Retail Level**.

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Zydus Pharmaceuticals USA Inc. advises its customers that have this product in stock to discontinue use/dispense/distribution and return it to Inmar Pharmaceuticals Services as per the details below.

We request that you please organize the return of the referenced drug product / lots in your possession and of course all costs associated with this recall shall be reimbursed by Zydus. To facilitate this recall, please do the following actions:

1. Examine your available stock for the presence of above referenced lots Divalproex Sodium DR Tablets USP 500mg.

2. If you have the concerned lot number drug product in your stock, please discontinue further distribution, quarantine the affected product and return all units to: Inmar Pharmaceutical Service, South Dock, 4332 Empire Rd, Fort Worth, TX 76155.A credit memo will be issued covering the quantity of 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 lot being recall, then also we appreciate if you fill out and return the "PRODUCT RECALL RESPONSE FORM"

4. If you have further distributed this product, please notify your customers at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

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

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

Should you have any questions or issues regarding this recall, please call recall services at 1-800-967-5952.

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

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

Yours Sincerely,

03/15/17

Prashant Desai
Sr. Vice President – Technical Operations

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PRODUCT RECALL RESPONSE FORM

URGENT DRUG RECALL- RETAIL LEVEL

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.

Product Details: Divalproex Sodium DR Tablets USP 500mg

Lot No.	Expiry	Pack Size	No. of Bottle Purchased	No of Bottles consumed	No. of bottles in Possession	No of Bottles to be returned
MR6187	05/17	500's				
MR7302	06/17	500's				
MR7768	07/17	500's				
MR7769	07/17	500's				
MR8221	07/17	100's				
MR8222	07/17	100's				
MR8247	07/17	500's				
MR8887	08/17	500's				
MR8892	08/17	500's				
MR8893	08/17	500's				
MR9014	09/17	500's				
MR10260	09/17	100's				
MR10414	09/17	500's				
MR10926	10/17	100's				
MR10928	10/17	500's				
MR11183	11/17	500's				
MR11185	11/17	500's				
MR11186	11/17	500's				

No. of Returns kit required: _____

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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.

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: _____