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

February 18, 2021

URGENT DRUG RECALL

Dear Customer:

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

Product	NDC Number	Lot Number	Expiry Date	Pack Size	Distribution Start Date	Distribution End Date
Acyclovir Sodium injection 50 mg/mL, 20 mL	68382-0049-10	L000155	Dec 21	10x20 mL, Single-Use Vial pack	Start Dt. 12/23/2020	End Dt. 01/05/2021
Acyclovir Sodium injection 50 mg/mL, 20 mL	68382-0049-10	L000156	Jan 22	10x20 mL, Single –Dose Vial pack	Start Dt. 01/07/2021	End Dt. 01/07/2021
Acyclovir Sodium injection 50 mg/mL, 10 mL	68382-0048-10	L000126	Dec 21	10x10 mL, Single-Use Vial pack	Start Dt. 12/23/2020	End Dt. 01/05/2021
Acyclovir Sodium injection 50 mg/mL, 10 mL	68382-0048-10	L000127	Dec 21	10x10 mL, Single-Use Vial pack	Start Dt. 01/07/2021	End Dt. 01/07/2021

Zydus Pharmaceuticals (USA) Inc. has decided to initiate a voluntary recall of the drug products mentioned above after receiving three complaints of similar nature ("Crystallization in Vials" in Acyclovir Sodium injection 50 mg/mL - both pack sizes of 10 mL and 20 mL. – Zydus Pharmaceuticals (USA) Inc. is recalling all commercially distributed batches out of an abundance of caution.

Our investigation of these product complaints is currently under process, and taking patient safety into consideration, it has been decided to proactively recall the above referenced batches. We wish to conduct this recall at the **Hospital Level**.

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.

Through this communication, at our cost, we request you to organize to return the above referenced drug products in your possession. To facilitate this recall, please complete the following actions:

1. Examine your available stock of Acyclovir Sodium injection 50 mg/mL, 10 mL and 20 mL as per above mentioned lot numbers.

2. If you have the concerned lot numbers of the drug product in your stock, please discontinue further distribution, quarantine the affected product and return all units to: Inmar

Pharmaceutical Service, 3845 Grand Lakes Way, Grand Prairie, TX 75050. 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, we would appreciate if you could still 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 the logistics for returning affected lots or other issues, please call Recall Services at 855-671-5023 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

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 during business hours Monday – Friday (excluding holidays), 9 am to 5 pm EST.

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

Sincerely yours,

02/18/2021

Srinivas Gurram (Srini)
Vice President & Head of RA & QA- North America
Zydus Pharmaceuticals (USA) Inc.