AMERICAN HEALTH PACKAGING®
An AmerisourceBergen Company

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URGENT PRODUCT RECALL

May 8, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Anastrozole Tablets, USP 1 mg 30 count Unit Dose Blisters, Carton NDC#: 60687-112-21, (Individual Dose NDC: 60687-112-11),** for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
Anastrozole Tablets, USP 1 mg 30 count Unit Dose Blisters **Carton NDC#: 60687-112-21** **(Individual Dose NDC: 60687-112-11)**	175289A	8/31/2019	1/17/2018 to 7/11/2018
	175286B	8/31/2019	4/11/2018 to 6/18/2018
	175290B	8/31/2019	7/11/2018 to 11/12/2018
	179906A	3/31/2020	11/12/2018 to 2/22/2019
	183252A	9/30/2020	2/1/2019 to 4/22/2019
	184611A	11/30/2020	4/22/2019 to 4/30/2019

REASON	This recall is being initiated in support of the recall by the manufacturer (Zydus) dated May 3, 2019, which included lots that were repackaged by American Health Packaging. Zydus stated that "In view of an ongoing USFDA inspection and an associated FDA observation at our Moraiya manufacturing site, Zydus Pharmaceuticals USA Inc has decided to proactively initiate a voluntary recall of multiple lots of the above referenced drug product. This recall is being initiated as a precautionary measure as though no evidence has been found in any product testing, we cannot rule out at this time cross contamination due to a GMP cleaning procedure failure in the Fluid Bed Dry Processor area."
HEALTH HAZARD EVALUATION	Anastrozole tablets are indicated for treatment of postmenopausal women with hormone receptor-positive early breast cancer. Based on the Health Hazard Evaluation performed by Zydus, although the risk to the general population is yet to be determined the risk of adverse event occurring is remote.

ACTIONS REQUIRED

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of these lots.
2. **Distributors** - Complete the enclosed Business Response Form even if you do not have any product on hand.
3. **Distributors** - Please pass this Recall Notice on **ONLY** to pharmacies that received these product lots.
4. **Pharmacies** - If you have units of the affected products/lots in inventory, please contact Inmar Pharmaceuticals Services at 800-967-5952 (option 1) to receive a Business Recall Response form or acquire it from clsnetlink.com.
5. Business Recall Response Form can be submitted by any of these methods.
   Fax: 817-868-5362
   Email: rxrecalls@inmar.com
   Address: Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101
6. **Distributors/Pharmacies** - Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.
7. **Pharmacies** - You do not need to contact any patients.

OTHER	This Recall extends to the Retail Level only. No other lots, packages, or formulations are being recalled. Please reorder stock immediately. For questions about the recall process, call Inmar Pharmaceuticals Services at 800-967-5952. This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

To receive credit, the reply form and recalled product must be returned to Inmar Pharmaceuticals Services by August 8th, 2019.

Thank you for your support in complying with the requests in this letter. We apologize for the inconvenience that this incident may cause you or your customers.

Sincerely,

Becky A Mahon

Becky A Mahon
Regulatory Specialist
American Health Packaging