AMERICAN HEALTH PACKAGING®
An AmerisourceBergen Company

Phone: (614) 492-8177
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URGENT PRODUCT RECALL

December 4, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Raloxifene Hydrochloride Tablets, USP 60 mg 30 count Unit Dose Blisters, Carton NDC#: 60687-266-21, (Individual Dose NDC: 60687-266-11),** for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Raloxifene Hydrochloride Tablets, USP 60 mg 30 count Unit Dose Blisters **Carton NDC#: 60687-266-21** **(Individual Dose NDC: 60687-266-11)**	180276A	02/29/2020	11/09/2018 to 04/04/2019

REASON	This recall is being initiated due to dissolution failure at 12-Month timepoint of the repackaged lot. Drug release results for were below specification at the 12-Month timepoint.
HEALTH HAZARD EVALUATION	Raloxifene hydrochloride tablets, USP are indicated for the treatment of osteoporosis in postmenopausal women

ACTIONS REQUIRED

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** - Complete the enclosed Business Reply Form even if you do not have any product on hand.
3. **Distributors** - Please pass this Recall Notice on **ONLY** to pharmacies that received this product lot.
4. **Pharmacies** - If you have units of the affected products/lot 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 by April 5th, 2020.

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