Phone: (614) 492-8177
Toll Free Phone: (800) 707-4621

URGENT PRODUCT RECALL

January 11, 2024

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Rifampin Capsules USP, 150 mg, 30 UD; Carton NDC#: 60687-575-21, (Individual Dose NDC: 60687-575-11),** for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Rifampin Capsules USP, 150 mg, 30 UD **Carton NDC#: 60687-575-21** **(Individual Dose NDC: 60687-575-11)**	1008111	01/31/2024	05/12/2022 to 05/18/2022

REASON	This recall is being initiated in support of the recall by the manufacturer (Lupin Pharmaceuticals, Inc.) dated January 05, 2024, which included lots that were repackaged by American Health Packaging. Lupin stated that "[Affected] lots are being recalled due to out of specification result observed in assay testing of all [affected] lots and related substance testing (N-Methyl Rifampin impurity) in lot A200816, Expiry: January 2024 during stability study. The reduction in the assay content may result in slight decrease in therapeutic effect (sub-therapeutic response). The toxicological properties of N-Methyl Rifampin impurity have not been extensively studied; thus, the health hazards cannot be conclusively assessed."
HEALTH HAZARD EVALUATION	Rifampin is a semisynthetic antibiotic derivative of rifamycin SV. Rifampin is indicated in the treatment of all forms of tuberculosis. Rifampin is indicated for the treatment of asymptomatic carriers of Neisseria meningitidis to eliminate meningococci from the nasopharynx.

ACTIONS REQUIRED

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** - Complete the enclosed Business Reply Card 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 Sedgwick at (888) 258-7910 to receive a notification package with the Business Reply Card and return instructions.
5. Business Reply Cards can be submitted by any of these methods.
   Fax: (888) 345-2652
   Email: AHP8300@sedgwick.com
   Mail: 6026 Lakeside Blvd. Indianapolis, IN 46278
6. **Distributors/Pharmacies** - Return recalled product to Sedgwick 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 Sedgwick at (888) 258-7910. 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 Sedgwick by April 30, 2024.

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 (Jan 9, 2024 15:56 EST)

Becky A Mahon
Sr. Regulatory Specialist
American Health Packaging