American Health Packaging®
An AmerisourceBergen Company

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URGENT PRODUCT CORRECTION

NOTE: THIS IS NOT A PRODUCT RECALL, PLEASE DO NOT RETURN PRODUCT.

August 27, 2019

Dear Valued Customer,

American Health Packaging, Inc. is contacting customers to inform them of an error in Package Inserts included in cartons of **AHP Lamivudine Tablets USP 150 mg 30 count Unit Dose Blisters, Carton NDC#: 60687-362-21 (Individual Dose NDC: 60687-362-11),** for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
Lamivudine Tablets USP 150 mg 30 count Unit Dose Blisters **Carton NDC#: 60687-362-21** **(Individual Dose NDC: 60687-362-11)**	186509	6/30/2021	7/29/2019 to 8/1/2019
	186982	6/30/2021	8/2/2019 to 8/8/2019

REASON	This Package Insert Correction is due to an error in the "**Dosage Forms and Strengths**" section of the insert (revision code 8436221/0619F) that incorrectly lists the tablet description coding for the tablets. Incorrect (8436221/0619F): **3 DOSAGE FORMS AND STRENGTHS** • Lamivudine Scored Tablets USP 150 mg, are white to off-white scored capsule shaped, film coated tablets, debossed on both tablet faces, such that, when broken in half "L" and "5" code is present on both halves of the tablet ("L" on one side and "5" on the opposite face of the tablet). • Lamivudine Tablets USP 300 mg, are gray colored capsule shaped, film coated tablets, debossed with "L" on one side and "6" on the other side. Correct (8436221/0819F): **3 DOSAGE FORMS AND STRENGTHS** • Lamivudine Tablets USP, 150 mg (Scored) White to off-white, film-coated, oval shaped tablets, debossed with '52' and 'Y' on either side of the score line on one side and plain with a score line on the other side. • Lamivudine Tablets USP, 300 mg White to off-white, film-coated, oval shaped tablets, debossed with 'C' on one side and '64' on the other side.
HEALTH HAZARD EVALUATION	This issue does not affect the safety and efficacy of the drug product itself.

ACTIONS REQUIRED

An updated package insert (revision code 8436221/0819F) is included in this mailing and can be obtained via http://dailymed.nlm.nih.gov/dailymed and at www.americanhealthpackaging.com.

Actions Required:

1. **Distributors** – Please pass this Correction Notice on **ONLY** to pharmacies that received these product lots.
2. **Distributors/Pharmacies** – Discard copies of incorrect insert and replace with corrected package insert
3. **Pharmacies** – Confirm that product information in electronic systems is accurate
4. **Distributors/Pharmacies** – DO NOT return product.

OTHER	This Correction extends to the Retail Level only. No other lots, packages, or formulations are being corrected. Please reorder stock immediately. This correction 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.

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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