March 10, 2025

IMPORTANT LABEL INFORMATION
Amneal Pharmaceuticals LLC
Temozolomide Capsules, USP, 250 mg

Subject: Typographical Error on Individual Folding Carton (IFC) of Temozolomide Capsules USP, 250 mg

Dear Healthcare Provider / Pharmacist:

The purpose of this letter is to inform you about a labeling inconsistency identified on the right-side panel of the Individual Folding Carton (IFC) of Amneal Pharmaceuticals LLC's Temozolomide Capsules, USP, 250 mg (NDC 65162-806-51).

- The following statement is *incorrect*: "Each capsule contains: **180** mg Temozolomide, USP".
- The statement should read as follows: "Each capsule contains: **250** mg Temozolomide, USP". This statement, which also appears on the bottle label, is correct.

This discrepancy does not affect the quality, safety, or efficacy of the drug product itself. All other information on the IFC, the bottle label, the Prescribing Information, the Patient Information, and the Pharmacist Information Sheet is accurate. This error impacted three lots:

Lot Number	Product Name and Strength	Expiration date
BJ01124A	Temozolomide Capsules USP, 250 mg	09/2026
BJ01224A	Temozolomide Capsules USP, 250 mg	09/2026
BJ01324A	Temozolomide Capsules USP, 250 mg	09/2026

Please refer to the enclosed full prescribing information for Temozolomide Capsules, USP, 250 mg indication.

It is important to note the following:

- Each capsule in the affected lots contains 250 mg Temozolomide, USP.
- The UPC barcode and NDC on both the carton and container labels correctly reflect the product strength (Temozolomide capsules, 250 mg)

Instruction for Healthcare Provider:
Please discard the IFC before dispensing Temozolomide Capsules, USP, 250 mg to a patient.

See below for illustrations of the IFC with *incorrect* statement, and the IFC with the *correct* statement:

Illustration 1: IFC of Temozolomide Capsules USP, 250 mg with the *incorrect* statement.

Illustration 2: IFC of Temozolomide Capsules USP, 250 mg with the *correct* statement.

REPORTING ADVERSE EVENTS

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

1. Complete and submit the report Online: www.fda.gov/medwatch/report.htm
2. Regular Mail or Fax: Download form https://www.accessdata.fda.gov/scripts/medwatch/index.cfm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

If you have additional questions, contact Amneal at:

- Phone: 1 (877) 835-5472 option 3
- Email: Drugsafety@amneal.com
- Mail: Amneal Pharmaceuticals, 50 Horseblock Road, Brookhaven, New York 11719

This letter is not intended to be a complete description of the benefits and risks related to the use of Amneal's Temozolomide Capsules USP. Please refer to the enclosed full prescribing information.

This letter is posted on Amneal's website at https://amneal.com.

Thank you in advance for your cooperation.

Ronald Sanwo, MD, MPH
Safety Physician / Associate Medical Safety Director
Phone number: + 1 877- 835- 5472
Email: Drugsafety@amneal.com