Amneal

Amneal Internal Ref # _____

August 28, 2026

STOCK RESPONSE FORM

Recall: Retail Level
Exenatide Injection, USP 250mcg/mL

Please fill out this form completely. By doing so, you acknowledge that you have read and understood the recall instructions and have taken the appropriate action.

Company Name _____

Address: _____

City: _____ State: _____ Zip Code: _____

Name of individual completing the form (please print) _____

Telephone number _____ Email: _____

Please check the appropriate box to describe your business,

☐wholesaler/distributor ☐ retail pharmacy ☐ hospital/medical facility ☐ hospital pharmacy

☐ Other (please specify) _____

I have checked my stock and (please check one):

_____Do not have any stock of the recalled items.

_____Have quarantined and listed in the box below the quantity of units I will be returning to Amneal. ***I will contact Amneal to obtain instructions for the return.***

NDC Code	Lot number	Expiration Date	1st Ship Date	Quantity being returned
70121-1685-1	AP250095A	02/2027	5/19/2025	

Please *promptly* complete this Recall Stock Response Form even if you have **no** product to return, and submit the completed form to Amneal by any of the below methods:

- Fax to: 631-983-2595
- E-mail to: ExenatideInjRecall@amneal.com
- Mail to: Exenatide Recall Coordinator, 21 Colonial Drive, Piscataway, NJ 08854

If you have any questions regarding this form or for instructions on how to return the product to Amneal, please contact Amneal at 1-833-582-0812; hours are 9am to 5pm EST, Mon thru Fri.

Amneal

URGENT: DRUG PRODUCT RECALL

Amneal Pharmaceuticals LLC
400 Crossing Blvd, Third Floor
Bridgewater, NJ 08807

August 28, 2026

Dear Valued Customer,

This letter is to inform you of a product recall involving:

Exenatide Injection, USP 250mcg/mL

This recall is being carried out to the Retail Level.

Amneal Pharmaceuticals LLC is initiating this voluntary recall of 1 lot of **Exenatide Injection, USP 250 mcg/mL (NDC 70121-1685-1)** due to potential for an autopen to be without medication.

Exenatide injection is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The recall is being conducted to remove affected product from distribution and prevent patient use of devices that may not contain medication.

The defect may result in failure to deliver the intended dose of exenatide, leading to therapeutic underexposure and loss of the expected glucose-lowering effect.

For help in identifying the product, please refer to the image below.

Only the 1 lot number listed in the table below is being recalled.

NDC Code	Lot number	Expiration Date	1st Ship Date	Last Ship Date
70121-1685-1	AP250095A	02/2027	05/19/2025	08/12/2026

Please immediately perform the following activities:

- Examine your inventory for the NDC number and Lot Number specified above and immediately discontinue distributing this product.
- Wholesalers/distributors, please inform your retail customers regarding the recall and provide the recall package with detailed instructions for product return.
- Promptly complete the attached Recall Stock Response Form ***even if you have no product to return*** and submit the completed Recall Stock Response form to Amneal by any of the following methods:

Amneal

- Fax to: 631-983-2595
- E-mail to: ExenatideInjRecall@amneal.com
- Mail to: Amneal Pharmaceuticals
  Exenatide Inj Recall Coordinator,
  21 Colonial Drive Piscataway, NJ 08854

- **Contact Amneal at 833-582-0812 Monday-Friday, 9:00 am-5:00 pm, EST for information on the recall or for information on the product return**
- This recall is being conducted with the knowledge of the U.S. Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated.

Medical Inquiries, Adverse Event Reporting or Quality Concerns

For Medical Inquiries or to report Adverse Events, or quality problems experienced with the use of this product, please contact Amneal Drug Safety by phone at 1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com.

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.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.