Amneal

URGENT: DRUG PRODUCT RECALL

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

November 13, 2026

Dear Valued Customer,

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

Dexmethylphenidate Hydrochloride Extended-Release Capsules, 10 mg

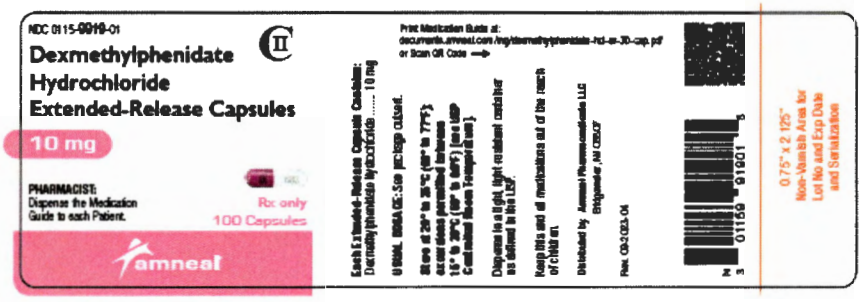
This recall is being carried out to the Retail Level.

Amneal Pharmaceuticals LLC is voluntarily recalling 20 lots of **Dexmethylphenidate Hydrochloride Extended-Release Capsules, 10 mg (NDC 0115-9919-01)** 100 count, due to the presence of FD&C Red No. 2 (amaranth), a color additive that is no longer authorized for use by the U.S. Food and Drug Administration (FDA). No other strengths are impacted on this recall.

Dexmethylphenidate HCL ER Capsules is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The health risk associated with ingestion of low levels of FD&C Red No. 2 (amaranth) depends on the amount consumed, frequency of exposure, and individual susceptibility. Animal studies have identified adverse effects, including kidney changes, following repeated exposure at higher doses; however, these findings do not establish that low-dose ingestion causes similar harm in humans.

For help in identifying the product, please refer to the following image:



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This recall applies to the 10 mg lots listed below.

Lot number	Exp. Date	1st Ship Date
BA12225A	11/2026	3/4/2025
BA12325A	11/2026	3/4/2025
BA12425A	11/2026	2/20/2025
BA12525A	11/2026	2/13/2025
BA36225A	01/2027	3/19/2025
BA36325A	01/2027	3/12/2025
BD22925A	03/2027	7/15/2025
BD23025A	03/2027	7/1/2025
BD23125A	03/2027	7/1/2025
BD23225A	03/2027	7/8/2025

Lot number	Exp. Date	1st Ship Date
BD23325A	04/2027	7/17/2025
BE03025A	04/2027	7/23/2025
BE03125A	04/2027	7/30/2025
BE03225A	04/2027	7/17/2025
BK14325A	10/2027	1/5/2026
BK14425A	10/2027	1/5/2026
BK14525A	10/2027	1/21/2026
BK14625A	10/2027	1/15/2026
BA13326A	01/2028	3/26/2026
BA13426A	01/2028	3/30/2026

Please immediately perform the following activities:

- Examine your inventory for the NDC number and Lot Numbers specified above and immediately discontinue distributing and quarantine the products.
- 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:

    - Fax to 631-983-2595
    - E-mail to: DexmethylphenidateERRecall@amneal.com
    - Mail to: Amneal Pharmaceuticals
      Recall Coordinator 9919,
      50 Horseblock Rd., Brookhaven NY 11719

- **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 of a controlled drug product. All recall shipments of controlled substances must comply with applicable DEA regulations.**

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.

Amneal

STOCK RESPONSE FORM

Amneal Internal Ref # _____

November 13, 2026

Recall: Retail Level

Dexmethylphenidate Hydrochloride Extended-Release Capsules, 10 mg (NDC 0115-9919-01)

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 _____ DEA # _____

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 _____

** NOTE: DO NOT return product until you have received the UPS Shipping Label(s) and DEA 222 form. A copy of the completed DEA 222 form is required to process your return.*

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.***

Lot number	Expiration Date	Quantity being returned (please be specific)
BA12225A	11/2026	
BA12325A	11/2026	
BA12425A	11/2026	
BA12525A	11/2026	
BA36225A	01/2027	
BA36325A	01/2027	
BD22925A	03/2027	
BD23025A	03/2027	
BD23125A	03/2027	
BD23225A	03/2027	

Lot number	Expiration Date	Quantity being returned (please be specific)
BD23325A	04/2027	
BE03025A	04/2027	
BE03125A	04/2027	
BE03225A	04/2027	
BK14325A	10/2027	
BK14425A	10/2027	
BK14525A	10/2027	
BK14625A	10/2027	
BA13326A	01/2028	
BA13426A	01/2028	

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: DexmethylphenidateERRecall@amneal.com
- Mail to: Amneal Pharmaceuticals, Recall Coordinator 9919, 50 Horseblock Road, Brookhaven NY 11719

An invoice or record must accompany each recall transfer and include, at minimum, the product name, strength, quantity, transaction date, and the names, addresses, and DEA registration numbers of both the supplier and recipient. Do not co-mingle with other products.

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.