U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via electronic mail with read and delivery receipt requested

October 27, 2026

Sham Garlapad
Vice President, Quality
Amneal Pharmaceuticals of New York LLC
50 Horseblock Road
Brookhaven, New York 11719
(b) (4)

To Mr. Sham Garlapad:

This letter advises you of violations identified during a U.S. Food and Drug Administration (FDA) review of records submitted from your facility and provides you an opportunity to address them. Promptly address any violations described herein without delay, including ensuring that appropriate resources are allocated to fully address the violations and prevent their recurrence. This is not intended to be an all-inclusive list of the violations that exist in connection with your products. It is your responsibility to ensure that you comply with all requirements of federal law, including FDA regulations. Failure to adequately address any violations may result in regulatory or legal action without further notice including, without limitation, seizure and injunction.

FDA Review

Violations were identified and documented during review of your drug manufacturing facility, Amneal Pharmaceuticals of New York, LLC, FDA Establishment Identifier (FEI) 3005263655. This review was conducted under FDA's statutory authority and public health responsibilities to protect the public from unsafe, ineffective, and poor quality drugs.

Your facility is registered with the FDA as a manufacturer of prescription drug products, including generic drugs. FDA has reviewed the records you submitted in response to our April 24, 2026, request for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for your facility.

Your dexmethylphenidate hydrochloride extended-release capsules (10 mg) drug product as described in your response to our 704(a)(4) is adulterated under section 501(a)(4)(A) as this drug product bears or contains a color additive that is unsafe within the meaning of section 721 of the FD&C Act, 21 U.S.C. 379e.

Violations of the Federal Food, Drug, and Cosmetic Act

The following are violations identified during our review. As a reminder, this is not an all-inclusive list of violations at your facility.

Drug Products Containing Cancelled Color Additive FD&C Red No. 2

You manufacture prescription drug products. Based on our review of records and your response to our records request, your dexmethylphenidate hydrochloride extended-release capsules, 10 mg contain the color additive “Acid Red 27” (also known as FD&C Red No. 2 or Amaranth). In 1976, FDA cancelled the certification and delisted FD&C Red No. 2 because it could not be proven safe for use. Under 21 CFR 81.30(j)(1), using FD&C Red No. 2 after January 28, 1976, results in the drug being adulterated. Accordingly, the introduction or delivery for introduction of your dexmethylphenidate hydrochloride extended-release capsules (10 mg) drug product into interstate commerce is a prohibited act under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Any color additive not explicitly listed as safe for its intended use is deemed unsafe within the meaning of section 721(a) of the FD&C Act. The inclusion of a delisted color additive in your drug product formulation indicates that your quality unit’s review (as required under 21 CFR 211.22) of your raw material qualification process and formulation review procedures is inadequate.

In response to our records request, you implemented inventory holds and suspended manufacturing and distribution of the dexmethylphenidate hydrochloride extended-release capsules 10 mg drug product. You also indicated your plan for reformulation of the product.

Drug Products Containing FD&C Red No. 3

Your response indicates you manufacture additional drug products containing FD&C Red No. 3 as an ingredient.

FDA revoked the authorization for the use of FD&C Red No. 3. Manufacturers who use FD&C Red No. 3 in ingested drugs will have until January 18, 2028, to reformulate their products. For more information see https://www.fda.gov/food/hfp-constituent-updates/fda-revoke-authorization-use-red-no-3-food-and-ingested-drugs.

We acknowledge your plan to reformulate your drug products before January 18, 2028, to no longer use FD&C Red No. 3.

Conclusion

As previously stated, you are responsible for investigating and determining the root causes of any violations and implementing corrective and preventative measures to ensure future and sustained compliance so that these violations and any others do not occur.

Send your written response to CDER-OC-OMQ-Communications@fda.hhs.gov within thirty (30) business days of receipt of this letter. Identify your written response with FEI 3005263655 and ATTN: Lynnsey Renn in the subject line of the email.

If you have information that you believe demonstrates that your products are not in violation of the FD&C Act and FDA regulations, include that information for our consideration.

Sincerely,

/s/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration