U.S. FOOD & DRUG ADMINISTRATION

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

Via UPS
Return Receipt Requested

June 2, 2026

Mr. Craig R Onofry
Vice President & General Manager
Port Jervis Laboratories, Inc.
20 W King St.
Port Jervis, NY 12771

Dear Mr. Onofry:

Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products. FDA has reviewed the records you submitted in response to our September 8, 2025 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, Port Jervis Laboratories, Inc., FEI 1317131, at 20 W King St, Port Jervis.

This letter summarizes violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding of drugs as described in your response to our 704(a)(4) request do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)).

Following review of records and other information provided pursuant to section 704(a)(4) of the FD&C Act, violations were observed including, but not limited to, the following:

1. **Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(1) and 21 CFR 211.84(d)(2)).**

Your firm manufactured (b) (4) an OTC (b) (4) drug product, labeled to contain the active drug ingredient (b) (4) This drug product is also labeled and formulated to contain the inactive ingredient talc. Both talc and asbestos are naturally occurring minerals that may be found in close proximity in the earth. Asbestos is a potential contaminant in talc and is a known human carcinogen when (b) (4) [1,2] (b) (4)

[1] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/asbestos
[2] https://www.atsdr.cdc.gov/asbestos/health-effects/

drug products are considered a higher-risk drug as it pertains to patient safety regarding asbestos contamination of talc due to the risk of inadvertent inhalation.

While your firm stated to have ceased to manufacture drug products containing talc in December 2023, we remain concerned about the adequacy of your incoming component testing and the processes used to validate supplier reliability at appropriate intervals.

You have not demonstrated that you appropriately tested incoming talc drug components used in the manufacture of (b) (4) drug products for identity, purity, strength, and quality. In response to our 704(a)(4) request, you indicate that you did not perform testing for asbestos in talc, and our review found that you do not conduct identity testing on talc prior to use in the manufacture of your drug products. You failed to provide records indicating that you established the reliability of your supplier's analyses through appropriate validation of the supplier's test results. Although 21 CFR 211.84(d)(2) provides for some reliance on a certificate of analysis (COA) from the supplier of the component, such reliance is permissible only if the drug product manufacturer establishes the reliability of the supplier's test results through appropriate validation of the test results at appropriate intervals. Without adequate testing, you lack scientific evidence that the components conform to appropriate specifications prior to use in the manufacture of your drug products.

Furthermore, the supplier's COA also failed to support testing for identification and absence of asbestos was conducted as per current United States Pharmacopeia (USP). Asbestos minerals are divided into two major groups: serpentine and amphibole.[3] The current USP talc monograph, which was in effect at the time of manufacture, procedures 1 and 2 require testing for the presence of amphiboles and serpentines. A representative COA from your supplier was reviewed. While the COA indicates that the attribute fibrous amphibole was tested, it did not contain testing for serpentine. Without adequate testing, you lack scientific evidence that the components conform to appropriate specifications prior to use in the manufacture of your drug products.

As a manufacturer, you have a responsibility to sample, test, and examine, as appropriate, drug components before use in production to ensure acceptable specifications for identity, strength, quality, and purity are met. Because you have not performed appropriate testing that detects asbestos in your talc components, among other things, you failed to assure the acceptability of these drug components for use in manufacture of your drug products.

In response to this letter, provide:

- Identity, assay and impurity test results from testing retains for all lots of talc (drug component) used in the manufacture of your drug products. Alternatively, if a retain of a component lot is unavailable, perform retain sample testing of all implicated finished drug product batches for asbestos. Provide this information within 30 calendar days of the date of this letter.

[3] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/asbestos/asbestos-fact-sheet

- A description of how you will test each component lot for conformity with all appropriate written specifications for identity, purity, strength, and quality. If you intend to accept any results from your supplier's COA instead of testing each component lot for strength, quality, and purity, specify how you will establish the reliability of your supplier's results through initial validation as well as periodic revalidation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot.

- A full risk assessment for drug products that are within expiry which contain any ingredient at risk for asbestos contamination. Take prompt and appropriate actions to determine the safety of all lots of the component(s) and any related drug product that could contain asbestos. Appropriate actions could include customer notifications and drug product recalls for any contaminated lots.

- The chemical quality control specifications you use to evaluate each incoming lot of drug component to determine acceptability for use in manufacturing.

- A gap analysis for specifications for drug components (active and inactive) between your current specifications and test procedures against the USP, where applicable. Based on your gap analysis, provide a comprehensive plan for conformance of your drug component specifications and testing to USP standards, where applicable.

- A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your standard operating procedure that describes this COA validation program.

2. Your firm's quality control unit failed to exercise its responsibility to ensure drug products are manufactured in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).

Your quality unit (QU) did not effectively exercise its responsibility to ensure the acceptability of your drug components. For example, your QU did not ensure that your test procedures and specifications for talc are scientifically sound and appropriate (see 21 CFR 211.160(b)). The current USP talc monograph could be used to meet this requirement for talc; however, specifications for talc components did not include testing for identity, assay, and multiple impurities (e.g., limits of (b) (4) Notably, you failed to have a specification that includes a test for the absence of asbestos. Your QU approved and accepted talc for use in drug manufacturing with deficient specifications.

Your QU is responsible for fully exercising its authority and responsibilities, including responsibility for approving or rejecting all procedures or specifications impacting the identity, strength, quality, and purity of the drug product. Your firm's quality systems are inadequate. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations*, for help implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR, parts 210 and 211 at https://www.fda.gov/media/71023/download.

In response to this letter, provide a comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:

- A determination of whether procedures used by your firm are robust and appropriate
- Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices
- A complete and final review of representative batches within expiry and their related information before the QU disposition decision

No Longer Manufacture or Distribute Drug Products Containing Talc

In your response to our request for records you indicated that as of December 2023, Port Jervis Laboratories, Inc. no longer manufactures or distributes any drug products containing talc. If you plan to resume production with drug products containing talc, notify this office in writing and include thorough documentation for asbestos testing.

Responsibilities as a Contractor

Drugs must be manufactured in conformance with CGMP. FDA is aware that many drug manufacturers use independent contractors such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer.

You are responsible for the quality of drugs you produce as a contract facility regardless of agreements in place with product owners. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act for safety, identity, strength, quality, and purity. See FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements* at https://www.fda.gov/media/86193/download.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 30 working days. Specify what you have done to address any violations and to prevent their recurrence. If you cannot complete corrective actions within 30 working days, state your reasons for delay and your schedule for completion. 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.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 1317131 and ATTN: Nancy Espinal.

Sincerely,

/s/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research