



May 6, 2025

Eric Longnecker  
Deputy Assistant Secretary for Technology Security  
Office of Strategic Industries and Economic Security  
Bureau of Industry and Security  
U.S. Department of Commerce  
14th Street and Constitution Avenue, NW  
Washington, D.C. 20230

**RE: Request for Confidential Treatment of Information Under FOIA Exemption 4 Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients; Docket No. 250414-0065; XRIN 0694-XC120**

Dear FOIA Officer:

Our company, Amneal Pharmaceuticals LLC ("Amneal"), is writing in response to your notification dated April 16, 2025, regarding a Freedom of Information Act (FOIA) request for records that contain confidential commercial and financial information that we have submitted to your agency. We respectfully request that the information described below be withheld from disclosure under Exemption 4 of the FOIA, 5 U.S.C. § 552(b)(4).

**Background Information**

On May 6, 2025, Amneal submitted public comments to the Office of Strategic Industries and Economic Security, Bureau of Industry and Security ("BIS"), in connection with BIS' request for public comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients; Docket Number 250414-0065; XRIN 0694-XC120. The submission contains detailed proprietary and confidential commercial and financial information that we maintain as strictly confidential and do not customarily disclose to the public.

**Description of Information to be Protected**

We request confidential treatment for the following specific information:

1. Detailed number of Amneal's FDA-approved products produced in the U.S. and overseas.
2. Detailed information describing the percentage of Amneal's total revenues derived from US-manufactured products.
3. Detailed information concerning the average wages for the Amneal manufacturing and quality teams in the U.S.

4. Detailed dollar amount of Amneal's investment in greenfield or repurposed manufacturing square footage and the number of states in which such square footage is located.
5. Detailed number of U.S. sites and the number of scientists employed in the U.S.
6. Detailed information concerning square footage in Hauppauge, NY.
7. Detailed information about additional dosages that Amneal could provide domestically based on proposed incentives.
8. Detailed information concerning the timing of Amneal's possible additional onshore production including years required to implement the production.

The specific documents and/or portions are identified in the attached index and redacted copies.

### **Legal Basis for Confidential Treatment**

Exemption 4 of the FOIA protects "trade secrets and commercial or financial information obtained from a person that is privileged or confidential." We demonstrate below that the information at issue meets the legal standards for protection.

#### **1. The information is commercial and financial in nature**

The information at issue is inherently commercial, as it relates directly to our business operations, specifically current and past production and related financial information that an existing or prospective competitor could exploit. This includes specific commercial elements like pricing, location of facilities, human resources costs and investment in facilities that are fundamental to our commercial enterprise.

#### **2. The information is obtained from a person**

The information was submitted by Amneal, a legal person under the FOIA.

#### **3. The information is confidential**

Under the standards established by the Supreme Court in *Food Marketing Institute v. Argus Leader Media* (2019), information is "confidential" within the meaning of Exemption 4 when it is (a) customarily and actually treated as private by its owner and (b) provided to the government under an assurance of privacy.

##### **a) Customarily and actually treated as private**

Our company maintains strict confidentiality over this information through the following measures:

- Restricting access to this information internally to only those employees with a need to know
- Requiring confidentiality agreements from all employees and contractors with access
- Employing technological security measures
- Never disclosing this information to the public or competitors
- Marking documents containing this information as "Confidential" or "Proprietary"

**b) Provided under an assurance of privacy**

We submitted this information to BIS with a clear expectation of confidentiality based on:

- Prior assurances from agency personnel that such information would be protected
- The nature of the submission process, which implied confidential treatment
- Markings of "Business Confidential" or "Proprietary" on all submitted materials
- The absence of any indication that the information would be publicly disclosed

**Substantial Competitive Harm**

While no longer required following the Argus Leader decision, we also note that disclosure would cause substantial competitive harm to our company. Specifically:

1. **Market Disadvantage:** Our competitors could use this information to determine Amneal's existing and future manufacturing investments.
2. **Pricing Vulnerability:** Disclosure of our manufacturing cost expenses would allow competitors to undercut our pricing strategy by determining where to manufacture competing products to undercut Amneal's cost structure.
3. **Strategic Exploitation:** Competitors could exploit knowledge of our strategic information to undercut Amneal's pricing and product strategies.

**Conclusion**

Based on the foregoing, we respectfully request that the identified information be withheld from disclosure pursuant to FOIA Exemption 4. The information is commercial and financial in nature, has been and continues to be treated as confidential by our company, and was provided to the government with an expectation of privacy. Should you have any questions or require additional information, please contact me at 908-409-6766 or [maryll.toufanian@amneal.com](mailto:maryll.toufanian@amneal.com).

Sincerely,

Maryll W. Toufanian ([maryll.toufanian@amneal.com](mailto:maryll.toufanian@amneal.com))  
Senior Vice President - Regulatory Strategy and Government Affairs  
Amneal Pharmaceuticals LLC

Enclosures:

1. Index of Documents/Information for Which Confidential Treatment is Requested
2. Redacted Copies of Responsive Documents

Index of Documents/Information for Which Confidential Treatment is Requested:

1. Amneal Pharmaceuticals LLC Response: Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients; Docket No. 250414-0065; XRIN 0694-XC120
2. Appendix 1
3. Appendix 2

Appendix 1

Redacted

Appendix 2

Redacted