Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

A Notice by the Industry and Security Bureau on 04/16/2025

This document has a comment period that ends in 21 days. (05/07/2025)

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Department of Commerce
Bureau of Industry and Security
[Docket No. 250414-0065]
XRIN 0694-XC120

AGENCY:

Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTION:

Notice of request for public comments.

SUMMARY:

The Secretary of Commerce initiated an investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended. Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES:

Comments may be submitted at any time but must be received by May 7, 2025.

ADDRESSES:

Comments on this notice may be submitted to the Federal rulemaking portal at: *www.regulations.gov (http://www.regulations.gov).* The *regulations.gov* ID for this notice is BIS-2025-0022. Please refer to XRIN 0694-XC120 in all comments.

All filers using the portal should use the name of the person or entity (printed page 15952) submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. The corresponding non-confidential version of those comments must be clearly marked "PUBLIC." The file name of the non-confidential version should begin with the character "P." Any submissions with file names that do not begin with either a "BC" or a "P" will be assumed to be public and will be made publicly available at: *https://www.regulations.gov (https://www.regulations.gov).* Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT:

Stephen Astle, Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-2533, *pharma232@bis.doc.gov (mailto:pharma232@bis.doc.gov)*. For more information about the section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232 (http://www.bis.doc.gov/232)*.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2025, the Secretary of Commerce initiated an investigation under section 232 of the Trade Expansion Act (19 U.S.C. 1862 (https://www.govinfo.gov/link/uscode/19/1862)) to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their

derivative products. This includes both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items.

Request for Public Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 (https://www.ecfr.gov/current/title-15/part-700) through 709 (https://www.ecfr.gov/current/title-15/part-709)) (“NSIBR”). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to BIS's Office of Strategic Industries and Economic Security no later than May 7, 2025. The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients;

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

(v) the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness;

(vi) the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction;

(vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies;

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security; and

(x) any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations (see the **ADDRESSES** section of this notice). Communications from agencies of the United States Government will not be made available for public inspection. The Bureau of Industry and Security does not maintain a separate public inspection facility. Requesters should first view the Bureau's web page, which can be found at: *https://efoia.bis.doc.gov/ (https://efoia.bis.doc.gov/)* (see “Electronic FOIA” heading). If requesters cannot access the website, they may call (202) 482-0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published at 15 CFR 4.1 (https://www.ecfr.gov/current/title-15/section-4.1) through 4.11 (https://www.ecfr.gov/current/title-15/section-4.11).

Eric Longnecker,

Deputy Assistant Secretary for Technology Security.
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