檔號		保存年限	
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經濟部國際貿易署　函

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裝

受文者：中華民國西藥代理商業同業公會

發文日期：中華民國114年4月21日
發文字號：貿雙二字第1147012111號
速別：普通件
密等及解密條件或保密期限：
附件：如文(1147012111-1.pdf)

主旨：有關美國商務部於聯邦公報(Federal Register)公告就啟動對進口藥品及藥物原料之232條款調查徵求公眾意見事，請查照並惠請轉知會員廠商。

訂

說明：

一、依據駐美國代表處經濟組114年4月16日經美字第1140000470號函辦理。

二、美國聯邦公報於本(114)年4月16日公布商務部通知，就進口藥品及藥物原料之232條款國家安全調查徵求公眾意見。

經濟部貿易署

三、上述通知要點如次：

(一)公眾意見截止日期為本年5月7日。

(二)該公告內說明，商務部長依據貿易擴張法232條啟動調查，以確定進口藥品、藥物原料及衍生品對國家安全的影響，包括學名藥及非學名藥成品、醫療對策(medical countermeasures)、包括活性成分(active pharmaceutical ingredients)與關鍵起始原料(key starting materials)等關鍵投入，以及上述項目之衍生品。

(三)商務部特別關切以下意見或資訊：

線

1、美國對藥品及藥物原料之目前和預期需求。
2、美國境內藥品及藥物原料生產能夠或預期能夠在何種程度上滿足國內需求。
3、外國供應鏈，特別是主要出口商，在滿足美國國內需求方面之角色。
4、美國藥品及藥物原料集中於少數供應商情形及相關風險。
5、外國政府補貼和掠奪性貿易行為對美國製藥產業競爭力之影響。
6、由於外國不公平貿易行為和國家支持之產能過剩而人為壓制藥品及藥物原料之經濟影響。
7、外國實施出口限制之可能性，包括外國將其對藥品供應鏈之控制能力武器化。
8、增加美國國內藥品及藥物原料產能以減少進口依賴之可行性。
9、現行貿易及其他政策對國內藥品及藥物原料生產之影響，以及是否有必要採取額外措施，包括關稅或配額，以保護國家安全。
10、任何其他相關因素。

四、檢送旨揭聯邦公報公告如附件，併請卓參。

正本：中華民國全國工業總會、中華民國西藥代理商業同業公會、中華民國西藥商業同業公會全國聯合會、臺灣藥品行銷暨管理協會
副本：駐美國代表處經濟組、經濟部產業發展署

署長劉盛廉

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)

PUBLISHED CONTENT - DOCUMENT DETAILS

Agencies: Department of CommerceBureau of Industry and Security
Agency/Docket Number: Docket No. 250414-0065
Document Citation: 90 FR 15951
Document Number: 2025-06587
Document Type: Notice
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PUBLISHED DOCUMENT: 2025-06587 (90 FR 15951)

DOCUMENT HEADINGS

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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