UNITED STATES DEPARTMENT OF COMMERCE
Under Secretary for Industry and Security
Washington, D.C. 20230

May 11, 2026

MEMORANDUM FOR: Mark Paoletta
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

FROM: Jessica Curyto
Deputy Assistant Secretary
for Technology Security
Bureau of Industry and Security

SUBJECT: Request for OMB Emergency Review and Approval of Information Collections for Section 232 National Security Adjustments to Imports of Pharmaceuticals

The Bureau of Industry and Security (BIS) is seeking approval to send the attached request to the Office of Management and Budget (OMB) for emergency clearance under the Paperwork Reduction Act (PRA) to allow the Department of Commerce, as represented by BIS, to publish a Federal Register Notice announcing the method by which companies will submit applications for tariff adjustments from certain *ad valorem* tariffs imposed on imports of pharmaceuticals and pharmaceutical ingredients under Section 232 of the Trade Expansion Act of 1962, as amended, on the basis of investment commitments to onshore manufacturing in the United States.

BACKGROUND

The strength of the U.S. pharmaceutical industry is vital to both civilian and military health. Heavy dependence on foreign supply chains creates serious vulnerabilities, increasing the risk of drug shortages, quality issues, and disruptions that threaten national security. This reliance on overseas manufacturing undermines the nation's ability to secure high-quality essential medicines for warfighters and to maintain reliable access to critical drugs during global crises or conflict.

On April 1, 2025, Commerce initiated an investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients under Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. § 1862). Section 232 provides authority for Commerce to conduct investigations to determine the effects of imports of an article on the national security of the United States and for the President to adjust the imports of the article and its derivatives based on such an investigation and an affirmative determination that the article is being importing into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States.

On April 2, 2026, following the completion of the above investigation, the President issued Presidential Proclamation 11020 entitled "Adjusting Imports of Pharmaceuticals and

Pharmaceutical Ingredients Into the United States" which imposed 100 percent *ad valorem* tariffs on imports of certain patented and branded pharmaceuticals and pharmaceutical ingredients, with a staggered effective date, beginning on July 31, 2026 for larger companies listed in Annex III of Proclamation 11020, and September 29, 2026 for all other companies. Proclamation 11020 also authorized Commerce to provide reduced tariff rates for imports of patented pharmaceuticals and associated pharmaceutical ingredients by companies that enter into agreements to onshore pharmaceutical production in the United States. The President determined that these actions were necessary to address the affirmative determination by Commerce that imports of pharmaceuticals and pharmaceutical ingredients posed to the national security of the United States. Per Proclamation 11020, the President found that such agreements further U.S. economic and national security interests by making pharmaceuticals more accessible and affordable in the United States and by strengthening the domestic manufacturing base.

Commerce is required to collect certain critical information from companies seeking to obtain tariff adjustments from the *ad valorem* tariff by submitting onshoring agreements to effectuate the terms outlined by Proclamation 11020. These collection requirements include detailed onshoring plans across product portfolios, percentage of U.S. sales that are made in the United States, investment and production milestones, and other information required to substantiate the applications for reduced tariffs under Section 232, hereby referenced as Tariff Adjustment Requests. This information will be submitted via email to Commerce. The materials will be reviewed by Commerce before Commerce enters into any agreements.

JUSTIFICATION

As the President has decided to adjust imports of pharmaceuticals and pharmaceutical ingredients and allow preferential tariff treatment for companies with Commerce-approved onshoring agreements, BIS requires emergency clearance from OMB to start collecting the information that would be required for parties submitting onshoring agreements to obtain tariff adjustments under the parameters outlined in Proclamation 11020 as soon as possible.

Per Proclamation 11020, the 100 percent tariff rate begins to go into effect on July 31, 2026 for larger companies listed in Annex III of Proclamation 11020, and September 29, 2026 for all other companies. BIS is requesting emergency PRA approval to start collecting information as soon as possible in order to incentivize more domestic manufacturing to maintain stability in the pharmaceutical industry, thereby reducing U.S. import reliance of pharmaceutical products. The entire onshoring agreement process, from BIS informing the public of the process through a Federal Register Notice (FRN), companies submitting the required information to BIS, reviewing and analysis of submitted information, and issuance of decisions based on information submitted from the public should be completed as quickly as possible. The FRN associated with this PRA collection allows companies to apply for onshoring agreements to increase domestic manufacturing of pharmaceutical products and their ingredients, which will increase the stability of the industry. Per Proclamation 11020, such companies are eligible for reduced tariffs. Approval criteria outlined in the FRN will help strengthen domestic industry while also protecting a vital supply chain. To prevent disruption, applications must be reviewed and approved before tariffs take effect, and staff will need sufficient time to complete their evaluations. Ensuring a timely process is critical to safeguarding both industry continuity and national resilience.

A delay in Commerce's ability to begin immediate information collection from companies seeking an onshoring agreement and inability to issue decisions before the 100 percent tariff rate is in effect could lead to companies delaying decisions to increase domestic manufacturing of pharmaceuticals, which would further import dependence that the Presidential Proclamation is seeking to reduce. Pending applications after the delayed effective date also creates uncertainty for companies' understanding of their tariff liability and could also cause supply chain disruptions.

In addition, actions of other agencies, such as the Customs and Border Patrol (CBP) and Health and Human Services (HHS), rely on the Commerce decisions on the onshoring agreement requests. CBP needs time to program the Ch. 99 HTSUS codes and importer of record information for each company that is granted an approved onshoring agreement by Commerce. Per Proclamation 11020, companies who enter into a most-favored nation drug pricing agreement with HHS and onshoring agreement with Commerce receive a zero percent tariff rate.

OMB's emergency clearance will allow BIS to publish a notice in the *Federal Register* informing the public how to submit such requests as soon as possible, which enables earlier decisions and greater certainty for industry on the impact of the remedies.

Sincerely,

JESSICA CURYTO

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