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0-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Section 232 National Security Adjustments to Imports of Specialty Pharmaceuticals and Associated Ingredients

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the OMB approved emergency collection for the Temporary Final Rule ***"Section 232 National Security Adjustments to Imports of Specialty Pharmaceuticals and Associated Ingredients"*** September 23, 2026, (91 FR 60360).

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Interested persons are invited to submit comments by email to Nancy Kook, IC Liaison, Bureau of Industry and Security, at PRA@bis.doc.gov or to PRAcomments@doc.gov. Please reference OMB Control Number 0694-0150 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Nancy Kook, IC Liaison, Bureau of Industry and Security, phone 202-482-2440 or by email at PRA@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

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 ad valorem tariffs on imports of certain patented pharmaceuticals and associated pharmaceutical ingredients. The Proclamation also directed a tariff rate of zero percent for certain designated specialty pharmaceutical products and their associated pharmaceutical ingredients, provided that Commerce (in consultation with the Office of the U.S. Trade Representative and Health & Human Services) determines that the products are either products of a jurisdiction that has a current or forthcoming trade and security framework agreement with the United States or otherwise meet an urgent health need 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 a threat to the national security of the United States.

Commerce will be required to collect certain critical information from companies seeking to obtain the ad valorem tariff rate of zero percent for imports of specialty pharmaceutical products and their associated pharmaceutical ingredients that meet an urgent health need in the United States. These collection requirements include organization information, a description of the imported product (including HTSUS Classification, Country of Origin, and Importer of Record)

and a detailed rationale of how the imported product meets an urgent health need in the United States (including information such as the type of disease treated and an assessment of alternative therapies or lack of alternative therapies for the type of disease the product treats, the number of domestic patients) as well as other information required to substantiate the applications under Section 232, hereby referenced as Urgent Health Need Requests. This information will be submitted via email to Commerce. The materials are reviewed by Commerce before receiving a final determination by the Secretary.

II. Method of Collection

Electronic

III. Data

OMB Control Number: 0694-0150.

Type of Information Collection: Regular submission

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 250.

Average Responses per Year: 1.

Average Number of Responses: 250.

Estimated Time Per Response: 8 hours.

Estimated Total Annual Burden Hours: 2,000 hours.

Respondent's Obligation: Voluntary.

Legal Authority: Section 232 of the Trade Expansion Act of 1962 (19 U.S.C. §1862)

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality,

utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

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