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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 260428-0115]

X-RIN 0694-XC155

Procedures To Apply for Company-Specific Onshoring Agreements to Obtain Tariff Adjustments for Pharmaceuticals and Pharmaceutical Ingredients Under Proclamation 11020

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

ACTIONS: Notice.

SUMMARY: This notice announces the procedures for companies that manufacture pharmaceutical products to apply for company-specific agreements with the Department of Commerce (Commerce) to onshore manufacturing of pharmaceutical products and their ingredients. Companies that enter into such agreements are eligible for a reduced Section 232 duty rate for imports of their pharmaceutical products and associated ingredients. Companies are requested to submit applications within 30 days of publication in the Federal Register.

DATES: Applications are requested by [INSERT DATE 30 DAYS FROM PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Applications must be submitted electronically to: pharma232@bis.doc.gov. Applications can be found at www.bis.gov/about-bis/bis-leadership-and-offices/SIES/section-232-investigations.

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) 482-4506, pharma232@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On April 2, 2026, the President issued Proclamation 11020 (91 FR 18183), "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients Into the United States," (Proclamation 11020) finding that imports of pharmaceuticals and pharmaceutical ingredients threaten to impair the national security of the United States and imposing tariffs to adjust imports of such products pursuant to Section 232 of the Trade Expansion Act of 1962 (Section 232). Proclamation 11020 imposed a 100 percent ad valorem tariff on certain imports of patented pharmaceuticals and associated pharmaceutical ingredients, effective September 29, 2026, for companies not listed in Annex III to Proclamation 11020. Lower rates apply to patented pharmaceutical products and associated ingredients from certain jurisdictions. At this time, Section 232 tariffs do not apply to generic pharmaceutical products and associated ingredients.

In clause (2) of Proclamation 11020, the President authorized the Secretary of Commerce (Secretary) to enter into company-specific onshoring agreements. Subparagraph (b) of clause (3) provides that companies with onshoring plans approved by the Secretary will receive a reduced duty rate of 20 percent. In addition, subparagraph (e) of clause (3) provides that this rate of duty shall be zero until January 20, 2029, for those companies that also enter into Most Favored Nation (MFN) deals with the U.S. Department of Health and Human Services (HHS).

Clause (6) orders the Secretary to establish a process by which companies can submit onshoring plans supporting eligibility for reduced duty rates. All onshoring plans are subject to approval, monitoring, and enforcement by the Secretary. Companies with qualifying onshoring

plans must submit periodic reports to Commerce regarding progress towards fulfilling onshoring milestones. Commerce may require that such reports be audited by an external auditing firm.

The Proclamation authorizes the Secretary to monitor and enforce onshoring agreements. It also provides that in cases where the executive branch assesses that a company engaged in fraud or deliberately misled the United States Government with respect to its onshoring commitments, Commerce may reimpose the tariffs introduced in Proclamation 11020 both prospectively and retroactively on imports from the relevant company, and it may impose other tariffs and penalties to the extent consistent with applicable law.

Consistent with Proclamation 11020, this notice establishes the criteria for company-specific agreements for the tariff adjustment program, including the application process, documentation and certification requirements, and eligibility conditions.

II. Application Process

Companies that market foreign-made patented pharmaceutical products and associated ingredients into the United States, which are subject to tariffs under Proclamation 11020, may apply to enter an onshoring agreement. Applications can be found at www.bis.gov/about-bis/bis-leadership-and-offices/SIES/section-232-investigations. Applicants must submit the application and associated documentation to pharma232@bis.doc.gov. The complete application should include the following information, with reference, as appropriate, to the relevant application section:

1. *Section 1 – Organization Information*: Full legal name, address, ownership structure and beneficial ownership, including the country where the company's headquarters is located. The name, title, and contract information of the authorized representative submitting the application should also be included. The company should also provide information about the products it manufactures and where such manufacturing takes place, and whether the manufacturing occurs in facilities that the company owns, contract manufacturers, or other.

2. *Section 2 – Total Investment*: The grand total of new investments to be made in the United States from January 20, 2025, to January 20, 2029. Specify the portion of the investment amount that pertains to new capital expenditure, such as brick-and-mortar manufacturing plants and buildings where research and development will take place, in the United States.

3. *Section 3 – Onshoring Commitment*: A comprehensive explanation of what part of the company's existing patented product portfolio it will onshore (products, volume, and value), including through the use of contract manufacturers. Companies are encouraged to onshore as much of their global production of pharmaceuticals, APIs, and upstream pharmaceutical ingredients as possible, by January 20, 2029. Companies may stipulate that projected onshoring timelines depend on expected Food and Drug Administration regulatory approval timelines, which should be described in the application.

4. *Section 4 – Percentage of U.S. and Global Sales Produced in U.S.*: The percentage of the company's U.S. sales of patented pharmaceuticals whose APIs are produced in the United States as of January 20, 2025, and the expected percentage of its U.S. sales that will be U.S.-made as of January 20, 2029. Companies should also state the percentage of their global sales that are U.S.-made as of January 20, 2025, and the expected percentage of their global sales that will be U.S.-made as of January 20, 2029. Information should be provided on both a unit and revenue basis.

5. *Section 5 – Investment Commitment*: The application should include the following:

(1) a description of what part of its patented product portfolio the company proposes not to onshore (products, value, and percentage) by January 20, 2029;

(2) a statement that it is commercially unfeasible to onshore these products, and an explanation as to why this is the case. Near-term expiration of patents, and pharmaceutical products with an extremely small market in the United States are relevant factors in this context;

(3) the estimated hypothetical cost to establish production facilities in the United States for these products described in paragraph (1) (without reducing the production of other products);

(4) a statement of the amount that the company commits to spend on new brick-and-mortar facilities in the United States by January 20, 2029, over and above and in addition to the onshoring commitment described in section 2 ("Onshoring Commitment") above. This expenditure can include new production machinery and retooling of existing facilities. However, it should not include research and development expenses or other operating expenses;

(5) investment and production milestones in Annex A through January 20, 2029, which are associated with the investment commitments in paragraph (4). For example, companies should indicate the expected start date, completion date, and location of any new construction projects. They should also indicate the total amounts of money associated with the Total Investment and Onshoring Commitment that they project to be spent by the end of each calendar year;

(6) a commitment to submit audited reports to Commerce at least semiannually regarding the company's progress towards fulfilling these milestones, as well as the U.S. investment commitments;

(7) a statement of whether the company has entered into, or is pursuing, a Most Favored Nation Pricing Agreement with the HHS; and

(8) a commitment to provide supporting information upon request by Commerce, whether before or after entering into the onshoring agreement.

5. *Annex A – Planned Pharmaceutical Production Investments*: This annex provides a template for companies to submit the information described above.

6. *Annex B – Tariff Adjustment*: In this annex, companies should provide the following information, with respect to products for which they request preferential treatment:

- HTSUS code (10-digit, if possible) for each product
- Advertised name and brand of product, as well as active ingredient (or combination of active ingredients)

- Country of origin of products imported under each HTSUS code
- Importer of record names and importer of record numbers
- Name and address of exporters
- Name, owner, and address of foreign manufacturing facilities
- U.S. Customs and Border Protection (CBP) Manufacturer Identification Code (MID) used for importations of products

Only patented pharmaceutical products and associated pharmaceutical ingredients should be included in Annex B.

7. *Certification*: Company applications should be signed by a senior official in the company. Applications shall include a certification, such as a sworn statement, from a senior officer of the company confirming that the submission is true, accurate, and complete to the best of the company's knowledge, under penalty of perjury, and confirming that the company has conducted reasonable diligence to verify the accuracy of the assertions and facts contained in its submissions.

8. *Representations and Acknowledgments To Be Included in the Application*: "[Drug Manufacturer] understands that any preferential treatment resulting from the submission of this application will apply only to Section 232 Tariffs (*i.e.*, tariffs pursuant to Proclamation 11020) on [Drug Manufacturer]'s-branded pharmaceutical products and associated pharmaceutical ingredients that [Drug Manufacturer] imports into the United States, as specified in this application. Furthermore, unless otherwise approved by Commerce, this preferential treatment shall not apply to any products produced by companies that [Drug Manufacturer] acquires after April 2, 2026, nor shall it apply to products that [Drug Manufacturer] may acquire or license after April 2, 2026, nor shall it apply to products that [Drug Manufacturer] has not itself developed as a majority participant. Any preferential tariff treatment that [Drug Manufacturer] receives pursuant to an onshoring agreement with Commerce is contingent on the President's grant of authority to Commerce under Section 232 of the Trade Expansion Act of 1962 to adjust

imports of certain pharmaceutical products through the imposition of tariffs and the President's determination to authorize the entry into force of agreements such as this one."

9. *Additional Information*: Any other information the applicant believes is necessary to facilitate Commerce's decision-making. If companies believe that any of the requirements outlined above are not appropriate for their particular situation, they should provide a detailed explanation.

C. Review and Approval Process

Commerce may request supplemental documentation or clarification. Commerce will make an individual, fact-specific, company-specific decision for each applicant. Commerce may respond to individual applications with questions, revisions, conditional approval pending applicant's acceptance of proposed modifications to the proposal, or approval of the proposal as submitted. There is no time limit for Commerce's decisions. Approved applicants will be notified in writing of approval. Relevant information from Annex B will be transmitted by Commerce to CBP. CBP will administer the tariff adjustment at the time of entry summary filing and may request additional documentation to validate entries.

D. Usage and Enforcement

Unless otherwise approved by Commerce, the reduced tariff treatment:

- Shall be used only by importers that the Drug Manufacturer identifies as approved to import its products, and that Commerce approves;
- Shall not apply to any products produced by a company that the Drug Manufacturer acquires after April 2, 2026; and
- Shall not apply to products that the Drug Manufacturer may acquire or license after April 2, 2026, nor shall it apply to products that the Drug Manufacturer has not itself developed as a majority participant.

E. Oversight and Adjustments

In accordance with clause (6) of Proclamation 11020, all onshoring plans are subject to approval, monitoring, and enforcement by Commerce. Commerce will monitor manufacturer and

importer compliance and communicate information regarding noncompliance to CBP, where appropriate.

F. Confidentiality

Commerce will protect the confidentiality of all information submitted by companies pursuing an onshoring agreement. The onshoring application as well as any eventual agreements will include the following confidentiality provision:

The Department of Commerce will protect the confidentiality of confidential, trade secret, and/or proprietary information excluding information in the public domain ("confidential information") provided by the Drug Manufacturer to the fullest extent allowed by law. For example, subject to applicable laws, such information would be protected from disclosure by the Trade Secrets Act, 18 U.S.C. § 1905, and under Exemptions 3 and/or 4 of the Freedom of Information Act ("FOIA") (5 U.S.C. § 552(b)(3), (4)). The Department of Commerce shall limit dissemination of Drug Manufacturer's confidential information to those persons within its organization and other executive branch agencies and entities who have a need to know such information to fulfill the purpose of this Commerce Agreement and who agree to be subject to the restrictions of this Commerce Agreement.

Drug Manufacturer may disclose the terms of this Commerce Agreement and make any other public written disclosure regarding the existence of, or performance under, this Commerce Agreement, to the extent required, in the reasonable opinion of Drug Manufacturer's legal counsel, to comply with applicable law, including without limitation the rules and regulations promulgated by the United States Securities and Exchange Commission or any other governmental authority, securities exchange or securities regulator to which it is subject.

These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General or the Office of Special Counsel of a violation of any law, rule, or regulation,

or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this Commerce Agreement and are controlling.

III. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB) approval and displays a currently valid OMB Control Number.

In Proclamation 11020 of April 2, 2026, "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States" the President determined it was necessary and appropriate to direct the Secretary of Commerce and the Secretary of Health and Human Services to pursue negotiations of agreements or continue any current negotiations of agreements to address the threatened impairment of the national security with respect to imported patented pharmaceuticals and associated pharmaceutical ingredients. The President authorized the Secretary of Commerce to enter into and implement company-specific onshoring agreements.

Because the Proclamation requires timely implementation of the onshoring agreements to 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, and reduce the national security risk posed by imports of patented pharmaceuticals and associated pharmaceutical ingredients, BIS cannot reasonably comply with the normal clearance procedures. Delaying this collection would impede the ability of companies to enter into onshoring agreements and compromise the effectiveness of the Proclamation's implementation. The implementation of an *ad valorem* tariff on imports of certain patented pharmaceuticals and

pharmaceutical ingredients, consistent with the intent of Proclamation 11020, also requires creating a process to allow any individual or organization in the United States to submit onshoring agreement applications for tariff adjustments. The Department has determined the following conditions have been met:

a. The collection of information is needed prior to the expiration of time periods normally associated with a routine submission for review under the provisions of the Paperwork Reduction Act in view of Proclamation 11020,

https://www.federalregister.gov/documents/2026/04/09/2026-06956/adjusting-imports-of-pharmaceuticals-and-pharmaceutical-ingredients-into-the-united-states

b. The collection of information is essential to the mission of the Department, in particular to allow 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 tariff treatment under Section 232, hereby referenced as Onshoring Agreements. The Onshoring Agreements, as described in this FRN, must be submitted in electronic form via email to the BIS Section 232 Pharmaceuticals Investigation Inbox (pharma232@bis.doc.gov). Onshoring Agreements may be submitted within 30 days of this FRN publication and all submissions are entirely voluntary on the part of the requesting companies.

c. Public harm is reasonably likely to result if BIS were to follow the normal clearance procedures before issuing this information collection. BIS needs time to get onshoring agreements in place before September 29, 2026, when the Section 232 tariffs for most companies will become effective. This information 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. 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.

Agency: Commerce Department.

Type of Information Collection: New Collection.

Title of the Collection: Section 232 National Security Adjustments to Imports of Pharmaceuticals.

Affected Public: Private Sector—Businesses.

Total Estimated Number of Respondents: [450].

Average Responses per Year: [1].

Total Estimated Number of Responses: [450].

Average Time per Response: 8 hours.

Total Annual Time Burden: [3,600].

OMB Control Number: [0694-0147].

Jessica Curyto,

Deputy Assistant Secretary for Technology Security.

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