

# BIS Issues Procedures for Onshoring Agreements to Mitigate 100% Tariffs on Patented Pharmaceuticals

## WRITTEN BY

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The U.S. Department of Commerce (Commerce), Bureau of Industry and Security (BIS), has issued a Federal Register [notice](#) (the Notice) describing procedures for companies that manufacture pharmaceutical products to apply for company-specific onshoring agreements under [Proclamation 11020](#) (the Proclamation). The Proclamation subjects imports of certain patented pharmaceuticals and associated pharmaceutical ingredients to tariffs imposed under Section 232 of the Trade Expansion Act of 1962 (Section 232) and authorizes the Secretary of Commerce to conclude onshoring agreements that qualify companies for reduced Section 232 tariff rates. The discussion below summarizes the resulting tariff structure and key dates, the application window and submission mechanics, the required content of onshoring agreement applications, BIS's review and enforcement framework, and related legal and transactional considerations.

## TARIFF STRUCTURE AND KEY DATES

The Proclamation establishes a 100% ad valorem Section 232 tariff on certain patented pharmaceuticals and associated pharmaceutical ingredients for companies not identified in Annex III to the Proclamation, effective September 29, 2026. The Proclamation also specifies reduced tariff rates for certain jurisdictions (e.g., EU, Japan, Korea, Switzerland, Liechtenstein, and the UK) and company-specific arrangements. At this time, Section 232 tariffs do not apply to generic pharmaceutical products and associated ingredients.

Companies with approved onshoring agreements are eligible for a reduced duty rate of 20% on covered patented pharmaceuticals and associated ingredients. Companies that both secure onshoring agreements and enter into most favored nation (MFN) pharmaceutical pricing agreements with the U.S. Department of Health and Human Services (HHS) may qualify for a 0% tariff rate on covered products until January 20, 2029.

## APPLICATION WINDOW AND SUBMISSION MECHANICS

The Notice states that companies marketing foreign-made patented pharmaceutical products and associated ingredients into the U.S. that are subject to tariffs under the Proclamation may apply to enter an onshoring agreement. Companies are requested to submit applications by June 12, 2026. Applications must be submitted electronically to [pharma232@bis.doc.gov](mailto:pharma232@bis.doc.gov), and application materials are available on the BIS Section 232 investigations [webpage](#). The Notice does not set a specific deadline for BIS to act on applications.

## CONTENT OF THE ONSHORING AGREEMENT APPLICATION

BIS describes the information that companies must submit to be considered for an onshoring agreement. The

required information includes:

- Applicant company and primary contact information;
- A description of current manufacturing operations for the covered products and associated ingredients, including locations and production capacities;
- Baseline information on the share of U.S. sales supplied from U.S.-produced active pharmaceutical ingredients (APIs) and the share of global production conducted in the U.S. (with specified baseline and target years);
- Proposed onshoring plans, including capital investments, new or expanded U.S. facilities, and timelines for shifting manufacturing of patented pharmaceuticals, APIs, and upstream ingredients to the U.S.;
- Quantitative targets for increasing U.S. production and U.S.-sourced APIs over the period January 20, 2025, through January 20, 2029, and detailed implementation schedules; and
- Product-level information for the pharmaceuticals and ingredients covered by the application, including tariff classifications, product descriptions, and trade parties.

The Notice also requires applicants to identify which portions of their patent and intellectual property (IP) portfolio they plan to locate in the U.S., and to explain how those plans align with proposed manufacturing onshoring. Applicants must list any products for which they do not intend to establish U.S. manufacturing and provide an explanation, including why U.S. manufacture would not be feasible. An authorized company official must certify the completeness and accuracy of the information submitted.

## **BIS REVIEW, MONITORING, AND ENFORCEMENT**

The Notice explains that BIS will review applications on a case-by-case basis and may request additional information from applicants. If BIS approves an onshoring agreement, it will transmit the relevant information to U.S. Customs and Border Protection (CBP) so that CBP can apply the adjusted duty rate to covered imports. The Notice provides that Commerce may monitor compliance with onshoring agreements, including through periodic reporting and other measures, and that material deviations from agreed commitments may result in changes to duty treatment, including termination of reduced tariffs and reversion to the default rate. For companies that also enter MFN pricing arrangements, public sources indicate that HHS will separately administer those agreements and that 0% tariffs are conditioned on both onshoring and MFN commitments.

## **BROADER LEGAL, TAX, AND STRUCTURAL CONSIDERATIONS**

Although the Notice focuses on procedures and required information, the described requirements may affect tax, IP, and transfer pricing arrangements. For example, the need to identify and potentially relocate segments of the patent portfolio to the United States may interact with existing IP holding structures, cost-sharing arrangements, and related-party licensing practices. Preferential tariff treatment generally does not automatically extend to products acquired after April 2, 2026, newly licensed products, or products where the applicant was not a majority participant in development, absent further approval by Commerce.

## **NEXT STEPS**

Based on the Notice and Proclamation, the following steps are grounded in the procedural requirements and timelines described above:

1. **Identify Covered Products and Tariff Exposure:** Review the Proclamation and annexes to determine which

patented products and ingredients are covered, and quantify expected exposure under the 100%, 20%, and 0% rates.

2. **Develop Onshoring Plans Consistent With BIS Requirements:** Prepare the required information on current manufacturing and sourcing, planned U.S. investments (2025–2029), onshoring timelines and targets, and IP localization.
3. **Assemble a Cross-Functional Team to Prepare the Application:** Coordinate input from legal, trade compliance, tax, IP, manufacturing, and finance to ensure a complete and accurate BIS submission.
4. **Consider MFN Pricing Arrangements in Light of 0% Tariffs:** Evaluate whether to pursue MFN pricing agreements with HHS, given the potential 0% tariff rate through January 20, 2029 and the company’s pricing and contracting strategy.
5. **Integrate Section 232 Considerations Into Transactions:** Incorporate Section 232 tariff and onshoring issues into diligence and post-closing planning for acquisitions, licensing transactions, and collaborations.
6. **Establish Reporting and Compliance Processes:** Implement internal processes to track performance against onshoring commitments and support BIS monitoring, periodic reporting, and audits.

## **BOTTOM LINE**

The Notice implements the onshoring agreement mechanism authorized by the Proclamation and provides a formal path for pharmaceutical companies to obtain reduced Section 232 tariffs on covered patented pharmaceuticals and associated ingredients, subject to detailed onshoring and IP localization commitments. The request that applications be submitted by June 12, 2026, and the specified tariff implementation dates, create a defined timeframe within which companies can evaluate their options and, if appropriate, seek company-specific agreements.

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