



FOR IMMEDIATE RELEASE

BIS TO CONDUCT ASSESSMENT OF U.S. ACTIVE PHARMACEUTICAL INGREDIENT INDUSTRIAL BASE

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WASHINGTON, D.C. – The U.S. Department of Commerce’s Bureau of Industry and Security (BIS), Office of Strategic Industries and Economy Security, in partnership with the Department of Health and Human Services’ (HHS) Office of Industrial Base Management and Supply Chain (IBMSC), announced today that the U.S. government is conducting a comprehensive assessment of the U.S. Active Pharmaceutical Ingredient (API) industrial base to gain an understanding of the supply chain network that underpins U.S. pharmaceutical manufacturing capabilities. The resulting information will allow the federal government to more accurately plan and develop funding strategies to help ensure the availability and security of the API supply chain and to raise awareness of current limited domestic manufacturing capabilities, among other potential issues.

In support of the assessment, BIS will survey hundreds of U.S. API manufacturers, distributors, suppliers, and customers using the BIS’s survey collection authority under section 705 of the Defense Production Act of 1950, as amended. BIS will deploy the API Industrial Base Survey to industry in winter 2024.

“Ensuring the health and competitiveness of the API industry is vital to U.S. public health security,” **said Assistant Secretary of Commerce for Export Administration Thea D. Rozman Kendler.** “When completed, the API assessment will provide the U.S. Government with valuable insights needed to safeguard the supply of essential medicines upon which millions of Americans depend.”

This joint effort will identify interdependencies between respondents, suppliers, customers, and U.S. government agencies while also benchmarking performance across multiple tiers of the API industry. As outlined in Executive Order 14017 *America’s Supply Chains*, the United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. Using this authority to survey the API industry will allow us to better understand this critical facet of our medical critical infrastructure.

FAQs

Q. Under what authority does the Bureau of Industry and Security conduct this survey?

A. The Bureau of Industry and Security (BIS) has authority under section 705 of Defense Production Act of 1950 (DPA) (50 U.S.C. 4555), as amended, to conduct research and analysis of critical technologies and industrial sectors to advance U.S. national security and economic competitiveness. BIS uses industry-specific surveys to obtain production, R&D, export control, employment, and other relevant data to inform U.S. government policies and proposals.

Q. What is the Office of Strategic Industries and Economic Security?

A. The Bureau of Industry and Security’s [Office of Strategic Industries and Economic Security](#) (SIES) utilizes its unique authority under the DPA to conduct research and analysis of critical technologies and industrial sectors to advance U.S. national security and economic competitiveness. The office uses industry-specific surveys to obtain production, R&D, export

control, employment, and other relevant data to inform U.S. government policies and proposals.

Q. Who requested the assessment?

A. The assessment was requested by HHS's Administration for Strategic Preparedness and Response (ASPR) to support its mission to build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capabilities.

Q. Is this an annual/repeated collection?

A. The API industrial base assessment is a one-time collection, not to be repeated. Nevertheless, organizations with diverse capabilities across the public health industry may be identified to participate in more than one BIS-administered assessment.

Q. What is Office of Industrial Base Management and Supply Chain?

A. [The Office of Industrial Base Management and Supply Chain \(IBMSC\)](#) is part of ASPR in HHS. IBMSC aims to build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capabilities by investing in medical product industrial base expansion capacities that can enable ASPR to respond to future public health emergencies.

Q. What will the information from the assessment be used for?

A. The information collected will enable the U.S. government to benchmark industry performance, identify supply chain vulnerabilities, and evaluate public health emergency preparedness and overall supply chain resilience. The survey results will be aggregated into a comprehensive report that presents the current state of the API industrial base, including existing supply chain vulnerabilities, production capacities, emergency response capabilities, and other key findings from the survey data analysis. The report will also propose recommendations that aim to improve the resiliency of the U.S. API industrial base and ensure public health emergency preparedness.

Q. What type of data will the assessment produce?

A. The survey will collect information related to production capabilities, sourcing practices, customers, supply chain disruptions, human capital, capital equipment, and research and development, among other variables. The resulting report will provide the U.S. government with detailed industry information that is otherwise not publicly available and necessary to effectively protect and strengthen the U.S. API industrial base.

Q. Has BIS conducted similar studies in the past?

A. Yes. Since 1986, BIS has conducted over 60 assessments and 150 surveys on a wide range of topics, including the U.S. defense industrial base, healthcare products, information and communications technology, microelectronics, and semiconductors, among others. To view public versions of previous BIS reports and surveys, please visit our [website](#).

Q. Will the findings from this assessment be publicly available?

A. A public version of the assessment report will be published on the BIS website by summer 2025. To safeguard the API supply chain and ensure the integrity of respondent information, the public report will only contain aggregate, non-identifiable data. Data provided by industry is deemed business confidential under the DPA and will remain exempt from Freedom of Information Act requests.

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