



**U.S. Department of Commerce
Bureau of Industry and Security
Office of Strategic Industries and Economic Security**



Active Pharmaceutical Ingredient Industrial Base Survey and Assessment Overview

The U.S. Department of Commerce's Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security (SIES) is surveying and assessing the U.S. Active Pharmaceutical Ingredients (API) industrial base. This study is being performed in partnership with the Department of Health and Human Services' (HHS) Center for Industrial Base Management & Supply Chain (IBMSC). The assessment will provide IBMSC with data-driven recommendations that may include identifying opportunities for increased collaboration between the U.S. Government and industry as well as U.S. allies and partners to ensure the availability and security of the API supply chain in the U.S. and abroad.

The principal goal of this survey and assessment is to gain a deeper understanding of the global supply chain network supporting U.S. API manufacturing and identify vulnerabilities such as single-source or single-region dependency, unfair trade practices, and regulatory constraints, among other issues.

An estimated 500 organizations affiliated with the U.S. API industry will participate in this mandatory data collection. Each organization's contribution is vital to ensuring a meaningful, robust analysis of the current state of the API industrial base, including existing supply chain vulnerabilities, production capacities, emergency response capabilities, and other key takeaways and trends from the survey data analyses. Additionally, the data will improve the resiliency of the API supply chain in the face of future public health emergencies.

Legal Protections and Requirements

SIES utilizes the Defense Production Act of 1950 (DPA), as amended, to both collect and protect the business proprietary information submitted by the survey respondents. Additionally, Executive Order 13603 delegate to the Department of Commerce the authority to assess the capabilities of the U.S. industrial base to support the national security and critical program needs and develop policy recommendations to improve the international competitiveness of specific domestic industries. The information collected from survey respondents may be used publicly only in aggregated form, meaning at no time will such reporting identify your specific organization by name nor disclose proprietary information. Survey response information is exempt from Freedom of Information Act (FOIA) requests.

Industrial Base Assessment Program

Since 1986, SIES 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 (ICT), microelectronics and semiconductors, NASA's rocket propulsion sector, and strategic materials, among others. The results of most of SIES' industrial base assessments can be found here: <https://www.bis.doc.gov/dib>.

For more information on the assessment and overall program, contact Erika Maynard, Acting Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security at Erika.Maynard@bis.doc.gov.