

**SUPPORTING STATEMENT  
U.S. Department of Commerce  
Bureau of Industry and Security**

**U.S. Active Pharmaceutical Ingredient Industrial Base Assessment  
OMB Control No. 0694-0119**

**A. Justification**

**1. Explain the circumstances that make the collection of information necessary.**

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 Ingredient (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.

This data is needed to assess the health and competitiveness of direct and indirect suppliers supporting the U.S. API industrial base and identify issues and challenges for consideration in the U.S. API industrial base supply chain risk management planning.

**2. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.**

BIS intends to survey approximately 500 organizations, including API manufacturers and the suppliers of Key Starting Materials (KSMs), intermediates, specialty and fine chemicals, and other critical inputs. This information will be used to afford IBMSC visibility into the current and prospective U.S. API industry, specifically, the supply chain impacts resulting from foreign sourcing dependencies, quality issues, workforce practices, consolidation within the industry, U.S. and foreign government support, supply chain disruptions, impacts of export controls, and more.

The survey is a one-time request. Both quantitative and qualitative information obtained from the survey will be compiled into a consolidated database for analysis by BIS. The qualitative questions, specifically, will be used to complement the statistical data. BIS will anonymize the data and share the insights with the broader industrial base to improve monitoring of industry's overall performance and raise awareness of shared risks to mission implementation.

BIS 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 delegates 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.

By virtue of the above-mentioned statute and executive order, BIS is the focal point for industrial base and critical technology analyses among civilian federal agencies, which includes mandatory data collection authority to carry out these assessment responsibilities. Since 1986, SIES has conducted over 60 assessments and 150 surveys on a wide range of topics. These studies review in detail those industries with challenges relating to employment/STEM, international competition and trade, financial performance, production, supply chain, investment, foreign sourcing and dependencies, and other factors influencing industry's ability to support end-users across commercial, defense, and other national security programs. This survey is designed to collect information that facilitates such in-depth analysis.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.**

To lessen the burden on respondents, BIS is encouraging firms to provide electronic responses in Excel format. Each respondent will receive a personalized distribution letter signed by BIS management and a project overview fact sheet which outlines the scope of information required. The letter will contain directions to the BIS survey landing page, where the respondent where both Excel and PDF version of the survey are housed.

The statistical data requested in the survey adheres closely to categories of questions and survey nomenclature common to the API industrial base. The relevance of these fields also has been verified through remote field-testing with stakeholders from academia, the U.S. government, and U.S. industry. Nearly all respondents will have the requested data stored on computer systems or within internal resources, allowing retrieval of the information to populate the survey response.

BIS has conducted numerous industry and technology surveys in the past 27 years and actively pursues the refinement and updates of its survey techniques and information technology to minimize the burden on the respondents.

**4. Describe efforts to identify duplication.**

In partnering with other agencies, BIS will avoid duplication of information being gathered. Most information that BIS collects from each industry or technology is not obtainable elsewhere. Some of the basic corporate data, such as address location, stock symbol and leadership profiles, is submitted by companies to the U.S. Census Bureau. However, the Census Bureau is precluded by law from releasing information on specific companies.

**5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.**

Participants in this collection include distributors and manufacturers of APIs and API critical

inputs. The survey is designed to minimize burden on all respondents. For small firms, BIS has developed and implemented estimate thresholds to relieve these entities from the obligation of responding to portions of the survey instrument. For example, small businesses may only have to provide financial data in aggregated figures, while the remaining survey respondents provide full balance sheet and income statement results.

Moreover, prior to submission to OMB, BIS makes every effort to minimize the information collection burden that a survey imposes on the public. For example, BIS circulates a draft survey to academic and government experts, as well as representatives of companies within the target industry or sector as a “field test.” Comments received are factored into the survey form. Additional inputs obtained from facility site visits and outside research are also added to the survey. The survey form, typically in Excel format, is constructed for clarity and ease of completion. Drop-down answer menus are used throughout the survey form to reduce the overall burden on industry, especially small businesses.

Additionally, to minimize the time needed to complete the survey form, questions are clearly labeled and grouped by subject. Most of the data requested is common organizational management information, requiring a reasonable amount of time to gather and insert. There are a minimal number of open-ended questions (typically the most time-consuming and low-yield format) that allow respondents to better explain their views on topics of concern. If, for any reason, the respondent cannot complete the survey in Excel format, BIS will work closely with the respondent to facilitate an alternate form of submission. Based on previous survey data collections, BIS expects most companies to respond electronically.

**6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.**

For evaluation of the U.S. API industrial base, a survey is the only method available to define the ecosystem of capabilities and relationships. Furthermore, the mandatory collection serves as the only method for BIS to carry out its responsibilities under the DPA and Executive Order 13603. Without the survey-based information, BIS could not obtain company specific information necessary to perform a robust, accurate evaluation of the U.S. API supply chain’s health and competitiveness. Examples of such information include financial information, respondent capabilities, key inputs, supplier information, employment, research and development, and industry challenges. The resulting data will allow both BIS and IBMSC to benchmark industry performance, identify key sole-source dependencies, identify supply chain disruptions, as well as evaluate public health emergency preparedness and overall supply chain resilience.

**7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.**

There are no special circumstances that will result in the collection of information in a manner inconsistent with the guidelines of 5 CFR 1320.6. Survey responses will contain business confidential information, all of which will be protected by the Bureau of Industry and Security (BIS) consistent with OMB guidelines and 15 CFR Part 702.

**8. Provide information of the PRA Federal Register notice that solicited public comments on**

**the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.**

The Federal Register notice is not applicable to this collection because it falls within the scope of the BIS generic authority entitled, “National Security and Critical Technology Assessments of the U.S. Industrial Base,” approved under OMB Control No. 0694-0119. This authority was renewed in September 2022 and is renewed every three years to support BIS industrial base assessment needs.

BIS staff developed the U.S. API supply chain survey in consultation with industry and government experts over a period of several months. The following is a list of individuals who participated in the survey design process:

#### U.S. Government

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#### Industry

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## **9. Explain any decisions to provide payments or gifts to respondents, other than**

**remuneration of contractors or grantees.**

This survey will not involve any payment or gifts to respondents.

**10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.**

The survey instrument, cover letter, and fact sheet all provide assurance to the respondents that the information collected through the survey will be deemed business confidential and will be treated in accordance with Section 705 of the Defense Production Act of 1950, as amended (50 USC § 4555). This section prohibits the publication or disclosure of such information unless the President determines that its withholding is contrary to the national defense.

Information submitted will not be shared with any non-government entity, other than in aggregate form, and the Department will protect the confidentiality of such information pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (FOIA) if it is the subject of a FOIA request. BIS, Office of Strategic Industries and Economic Security has a long and successful track record in protecting confidential business information collected pursuant to the Defense Production Act.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.**

This survey will not collect information that could be construed as being of a sensitive nature, such as information concerning sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered sensitive or private.

**12. Provide an estimate in hours of the burden of the collection of information.**

BIS estimates that the total burden placed on respondents participating in the U.S. API survey will be approximately 10,000 hours. This estimate is based on a sample of 500 respondents with an average completion time of 20 hours per survey. This burden estimate is subject to variations among respondents because of differences in product/service participation, record keeping, company size and type, and other variables.

The estimate is based on BIS's overall past experience, as well as specific feedback from industry participants, including the U.S. defense industrial base, healthcare products, information and communications technology (ICT), microelectronics, rocket propulsion, strategic materials, underwater acoustic transducers, and others. The projected burden estimate of future surveys includes feedback obtained from these respondents.

The estimated total cost to respondents of this data collection is \$550,000. This estimate was calculated by assuming the average wage of \$55 per hour (average wage of pharmaceutical plant manager via ZipRecruiter) multiplied by the total burden hours of 10,000.

**13. Provide an estimate of the total annual cost burden to the respondents or record-**

**keepers resulting from the collection (excluding the value of the burden hours in Question 12 above).**

Not applicable.

**14. Provide estimates of annualized cost to the Federal government.**

The estimated annual cost to the Federal government for the survey is \$991,072. A significant portion of the cost relates to the survey questionnaire, which includes preparing, collecting, verifying, tabulating, and analyzing the data. Other costs are incurred in field testing the survey, developing findings and recommendations, preparing reports, and report printing and distribution. The direct employee costs are estimated by assuming one GS-15 Step 3 (\$84.08/hour + 35% benefits) one GS-12 Step 3 (\$50.87/hour + 35% benefits) and four GS-11 Step 1 (\$39.79/hour + 35% benefits) (based on the January 2024 OPM schedule) federal employees were assigned full-time to the assessment. The annual costs are calculated as follows:  $((\$84.08/\text{hour} + \$29.43) \times 40 \text{ hours/week} \times 52 \text{ weeks} = \$236,100) + ((\$50.87/\text{hour} + \$17.80) \times 40 \text{ hours/week} \times 52 \text{ weeks} = \$142,843) + ((\$39.79/\text{hour} + \$13.93) \times 40 \text{ hours/week} \times 52 \text{ weeks} \times 4 \text{ persons} =) = \$446,950$ . Indirect or overhead costs associated with the project are calculated as 20 percent of the direct employee costs, or \$165,179. A review of BIS budgets from previous years indicates costs for building maintenance, telephone, computers, and space rental charges generally cost about 20 percent of total employee costs.

The total estimated annual costs to the federal government are as follows:

Federal Employee Salaries (7 full-time employees)	\$825,893
Federal Government Overhead @ 20%	\$165,179
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<b>Total:</b>	<b>\$991,072</b>

**15. Explain the reasons for any program changes or adjustments.**

Because the scope of this collection of information falls within BIS's generic authority "DOC/BIS National Security and Critical Technology Assessments of the U.S. Industrial Base," (Control Number 0694-0119), there is no increase in burden hours being requested.

BIS has used this authority five times since its renewal in 2022. After the expected 10,000 burden hours attributed to the U.S. API industrial base assessment, BIS will have a remainder of 253,750 burden hours.

**16. For collections whose results will be published, outline the plans for tabulation and publication.**

The data collected by BIS will be aggregated to protect the confidentiality of respondent information. Any public report will contain aggregated data only.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.**

Not applicable. BIS will display the expiration date of this information collection authority Control Number 0694-0119 on all surveys and instructional information the public receives.

**18. Explain each exception to the certification statement.**

Not applicable.

**B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

Not applicable.