

SUPPORTING STATEMENT
U.S. Department of Commerce
Bureau of Industry and Security
Industrial Base Assessment: Healthcare Foreign Sourcing
and Dependencies
OMB Control No. 0694-0119

A. Justification

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

The Bureau of Industry and Security (BIS), Office of Technology Evaluation (OTE), is undertaking an industrial base assessment of the U.S. Healthcare and Public Health sector in coordination with the Department of Homeland Security (DHS), Homeland Infrastructure Threat and Risk Analysis Center. This project was initiated by DHS to determine foreign sourcing, critical dependencies and other supply chain issues that could inhibit the delivery of effective medical services in the United States (see attached letter).

The Healthcare and Public Health industrial supply chain is made up of manufacturers and distributors that are divided into three main market segments - medical devices, medical equipment and pharmaceutical products. Each segment of the sector could have potential vulnerabilities due to the host of market driven interdependencies resulting from international partnerships, single and sole-source manufacturers, limited visibility into, and control of, complex global supply chains and other factors. Through the successful collection and analysis of healthcare data from this project, DHS will be better able to foresee and plan for potential challenges to supply chains.

Recent examples of healthcare supply chain foreign dependencies were exposed during the fall/winter of 2009 when H1N1 vaccines and related delivery products were in short supply in the U.S. Other examples of critical foreign dependencies include cases where a category of blood thinner medicine was in short supply in the U.S. as offshore imports were determined to be counterfeit and potentially fatal to the patients. Lastly, radioactive isotopes used for a variety of medical treatments and tests were also in short supply due to total offshore dependence in numerous categories of isotopes.

Assisting OTE in this survey and assessment are representatives from a variety of agencies and organizations including the Department of Health and Human Services, Food and Drug Administration and a few local hospitals. A number of private companies are also providing

insight regarding the impact of foreign sourcing and dependencies on the healthcare sector including Glaxo Smith Kline, McKesson and 3M Corporation.

The proposed survey and assessment will assist OTE and DHS analysts in better understanding the current supply chains being utilized and the future challenges facing this important sector as non-U.S. sourcing continues to grow. The final report will also assist U.S. industry monitor trends, benchmark performance and raise awareness of potential foreign sourcing and dependencies that could inhibit delivery of healthcare products and services when needed. Together industry and government decision-makers can better prepare and plan for contingencies which may negatively impact the U.S. healthcare sector.

OTE has authority under Section 705 of the Defense Production Act of 1950, as amended and Executive Order 12656, to conduct assessments and collect information from industry in support of the U.S. industrial base. These assessments are normally undertaken at the request of the Department of Defense, with one or more of the Armed Services participating, or with other federal agencies. They usually focus on industrial, financial and economic issues affecting specific key industrial sectors or critical technologies. The enclosed survey questionnaire, which covers the period 2007-2010, is the primary source of information needed for an industrial base assessment of this type.

The information gained from the survey will be used to: 1- quantify and assess the state of the foreign sourcing and dependencies in medical devices, medical equipment and pharmaceutical products that are essential for delivery of U.S. medical services; 2- document key materials, products and services across all portions of the sector that could cause vulnerabilities in the U.S. healthcare supply chain; and 3- provide government and industry representatives with a comprehensive picture of this critical sector to better prepare and plan for contingencies which could negatively affect the U.S.

OTE is the focal point for industrial base and critical technology analyses among civilian Federal agencies by virtue of the above mentioned statute and executive order, which includes mandatory data collection authority to carry out these responsibilities. OTE has conducted approximately 42 assessments of this nature in the past 20 years under various related defense industrial base programs. Assessments generally review in detail those industries experiencing employment, international competition, financial, production, investment, foreign sourcing and dependencies and other difficulties in their ability to support the industrial base, including defense and national security programs. The survey document is designed to collect information that facilitates this kind of in-depth analysis.

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.

OTE intends to survey approximately 700 companies representing various segments of the U.S. Healthcare and Public Health sector – medical devices, medical equipment and pharmaceutical products. The survey is a one-time only request. Quantitative data obtained from the survey will be compiled into an aggregate database for analysis and eventual publication. This data is needed to assess trends in production, sales and exports, market share, international competition, export controls and foreign sourcing and dependencies. Qualitative questions are used in some cases to complement the statistical data. Using the aggregated survey data, the overall goal is to enable the private sector and government agencies to monitor trends, benchmark industry and government performance, and raise awareness of the implications regarding foreign sourcing and dependencies in the U.S. Healthcare sector which could inhibit the delivery of effective medical services.

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, OTE is encouraging the firms to provide electronic responses. Each respondent will receive a personalized letter which outlines the requirements of the study and the scope of information required. The letter will also contain directions to a secure website where the respondent can gain access to the Excel survey application. This approach was used successfully in a 2008 Counterfeit Electronics, 2010 Encryption Products, and 2010 NASA Supply Chain surveys. All three surveys were reviewed and approved by OMB.

The statistical information requested in the survey tracks closely with categories and groups commonly used in the industry and verified by field-testing the OTE survey. Most firms and organizations will have the information computerized and will be able to retrieve it in the form requested on the survey. Other questions will require thought and perhaps discussion among several individuals for proper responses. These questions do not lend themselves to standardized computer automation. However, the questions only require brief responses in the text boxes provided.

4. Describe efforts to identify duplication.

The information sought in the survey is unique and not available from any other source, either public or private. Some of the basic corporate background data requested is submitted by firms in a statistical sample 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.

While the majority of Healthcare manufacturers and distributors are medium and large size firms, this survey will be distributed to a number of small businesses. The electronic survey instrument was designed to minimize the burden on all respondents. If for any reason the respondent cannot complete the survey in Excel, OTE will work with the respondent on an alternate form of submission. However, due to the world class status of the U.S. Healthcare sector, we are expecting almost all firms 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.

In the case of this industrial base assessment of the U.S. Healthcare and Public Health supply chain network, a survey is the only method available for OTE to carry out its responsibilities under the Defense Production Act of 1950, as amended, and Executive Order 12656. Without the information gathered from the survey, OTE could not: 1- quantify and assess the state of the foreign sourcing and dependencies in medical devices, medical equipment and pharmaceutical products; 2- document key materials, products and services across all portions of the sector that could cause vulnerabilities in the U.S. healthcare supply chain; and 3- provide government and industry representatives with a comprehensive picture of this critical sector.

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, which will be protected by the U.S. Department of Commerce, Bureau of Industry and Security.

8. Provide a copy 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 is renewed every three years (last renewed in 2010) to support on-going BIS defense industrial base assessment needs.

OTE staff developed the survey in consultation with industry and government experts over a period of several months. The following is a list of those individuals who provided input and advice:

Government

Danielle Dean, U.S. Department of Homeland Security - 202-282-8689
Nitin Natarajan, U.S. Department of Health and Human Services – 202-260-2002
Steve Curren, U.S. Department of Health and Human Services – 202-260-1241

Companies

Megan M. Ivory, 3M Corporation – 202-414-3042
Christin Morris, Abbott Laboratories – 202-378-2020
William D. McLaury, Novartis Pharmaceuticals Corporation – (862) 778-7115

Organizations

Dr. Anthony Macintyre, George Washington University Hospital – 202-741-2911
Thomas M. Phan, Healthcare Distribution Management Association – 703-787-0000

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; however, copies of the completed public version of the Industrial Base Assessment: Healthcare Foreign Sourcing and Dependencies will be provided to the respondents upon request.

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

The survey and its cover letter provide assurances 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 U.S.C.A. app. Section 2061 et. seq.). This section prohibits the publication or disclosure of such information unless the President determines that its withholding is contrary to the national defense. The survey will be administered and the data collected via a secure internet server. Information submitted will not be shared with any non-government entity, other than in aggregate form, and the U.S. Department of Commerce will protect the confidentiality of such information pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (FOIA), should it be the subject of a FOIA request. OTE has a long and successful track record of protecting business confidential information collected under the above statute.

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.

OTE estimates that the total burden placed on the respondents by this Healthcare Foreign Sourcing and Dependencies Assessment survey effort will be approximately 9,100 hours. This is based on distributing surveys to 700 respondents with an average time of 13 hours needed to complete the survey.

This burden estimate is subject to variations among individual respondents because of differences in record keeping, organization size, and other variables. The estimate is based on the past experience of OTE, as well as feedback from companies and organizations that have completed our surveys. OTE has conducted surveys of various industries, including imaging and sensors, biotechnology, cartridge and propellant actuated devices, space industry, counterfeit electronics, 5-axis machine tools, microelectronics, encryption products and others.

The estimated total cost to respondents of this information collection is \$318,500. This estimate was calculated by assuming a respondents' average work rate of \$35 per hour multiplied by the total burden hours of 9,100.

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).

This item is not applicable because the survey questionnaire will not impose any annual costs on respondents involving capital and start-up costs or affect the costs of operation, maintenance, or purchased services.

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

The estimated cost to the Federal government for the survey is \$123,039. A major portion of this cost is related to the survey questionnaire, which includes preparation, collecting and verifying the information, and analyzing the data. Other costs will be incurred in summarizing the analysis and findings, preparing the final report, and report printing and distribution. The direct employee costs were estimated by assuming the hours spent on the project as about three-quarters year equivalent, or 39 weeks and taking three-quarters the annual pay of one GS-14, step 10. The direct employee cost is \$102,533.

Indirect or overhead costs associated with the project are calculated as 20 percent of the direct employee cost, or \$20,506. A review of OTE budgets from previous years indicates costs for building maintenance, telephone, computers, and space rental charges generally run about 20 percent of total employee costs.

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

Because the nature of this collection of information falls within BIS's generic authority entitled, "DOC/BIS National Security and Critical Technology Assessments of the U.S. Industrial Base," (OMB Control No. 0694-0119), there is no increase in burden hours. This is the third time BIS has used this authority in FY2010 (a total of 24,000 authorized annually). An unused balance to the authority of 20 annual burden hours (9,120 minus 9,100) will remain if the assessment is approved under this authority.

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

All data collected will be aggregated before publishing to protect company confidentiality. The surveys will be provided electronically to the 700 companies in late September/October 2010. The analysis and report writing will be started in January 2011, a draft report prepared by the end of March 2011. The final report is planned for publication in April 2011.

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 on all survey and instructional instruments the public receives.

18. Explain each exception to the certification statement.

Not applicable.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Attachment: U.S. Department of Homeland Security, Letter of Cooperation