

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0690-0030)

TITLE OF INFORMATION COLLECTION: BIS Public Health Industrial Base Survey (PHIB).

PURPOSE: To requests comments from the public to assist Commerce in preparing this report on the condition of the PHIB and recommend policies and actions to strengthen the PHIB.

On August 6, 2020, President Trump issued Executive Order 13944, *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States*. EO 13944, under section 1, stated that the United States must protect U.S. citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong PHIB with resilient domestic supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States.

As used in EO 13944, “Essential Medicines” are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of EO 13944. As used in EO 13944, “Medical Countermeasures” means items that meet the definition of “qualified countermeasure” in section 247d–6a(a)(2)(A) of title 42, United States Code; “qualified pandemic or epidemic product” in section 247d–6d(i)(7) of title 42, United States Code; “security countermeasure” in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations. See EO 13944, under section 7, for additional definitions used in this order, *e.g.*, “Active Pharmaceutical Ingredient,” “Advanced Manufacturing,” “API Starting Material,” “Critical Inputs,” “Finished Device,” “Finished Drug Product,” “Healthcare and Public Health Sector,” and “Qualifying Countries.” These definitions are also applicable to this notice.

Further, EO 13944, under section 1, stated that these domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID–19. It is critical that the United States reduces its dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation’s PHIB to respond to these threats. It is therefore the policy of the United States to:

- (a) accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs;
- (b) ensure long-term demand for Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States;

(c) create, maintain, and maximize domestic production capabilities for Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense; and

(d) combat the trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third party online sellers involved in the government procurement process.

Definition of Public Health Industrial Base (PHIB)

The capability to domestically manufacture or produce medical products, including medical devices, medical equipment, medical countermeasures, and medications, pharmaceutical products, and other products designed to improve patient outcomes. This includes the manufacturing of components and materials that are essential to create the final medical products, as well as ancillary supplies and disposable consumable products.

For medical devices and medical equipment, this includes all components that, if replaced by an equivalent alternative component, would require an amendment to the final product’s 510(k) certification. For medications and pharmaceutical products, this includes the drug finishing (*i.e.*, fill-finish, tableting, or capsule formulation), as well as the active pharmaceutical ingredients, and the key starting materials that are used to make the API. For blood products and medical products derived from animals (such as porcine and bovine heparin), this includes all aspects of the extraction, processing and formulation supply chain. For vaccines and biologics, this includes research and development, as well as the production of all components of the end product without which the end product would be ineffective for its intended purpose.

This also includes the labor force necessary to conduct the manufacturing operations described above. It does not include the ability of distributors to source medical products from foreign sources to distribute to the healthcare system in the United States.

The Department is particularly interested in comments and information directed to the policy objectives listed in EO 13944 as they affect the U.S. PHIB including, but not limited to, the following:

Survey Questions:

1. What do you believe is the condition of the current U.S. PHIB? Commenters in responding to this question are encouraged to reference their position in the PHIB.
2. What policies and actions would you recommend to strengthen the PHIB in the United States?
3. What aspects or parts of the PHIB do you see as being most vulnerable when involving outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats? In responding to this, commenters are encouraged to include their lessons learned from confronting COVID-19 or other historic pandemics and the needed ramping up of U.S. capacity in various areas to meet these challenges.

4. For the Essential Medicines, Medical Countermeasures, and Critical Inputs that your organization is involved with under the PHIB what percentage of these items are you dependent on from foreign suppliers? In responding to this question, also address if there are foreign dependencies in parts of your supply chain for critical inputs (*e.g.*, active pharmaceutical ingredients (APIs)) as well as finished products? In responding to this question, also address whether it would be possible to source those same items from the U.S. and how long you anticipate it would take to source these items from U.S. suppliers if your foreign supply was no longer available?
5. Are there any cost, regulatory, or other factors that make it more difficult or impossible to produce in or source from the United States for Essential Medicines, Medical Countermeasures, and Critical Inputs? In addressing this question, include any suggestions that you may have for how these concerns regarding sourcing or producing these items in the United States compared to sourcing or producing them outside the United States? In addressing this question, does your organization have mechanisms to determine whether Essential Medicines, Medical Countermeasures, and Critical Inputs are produced in the United States, and any limitations to those mechanisms? Commenters are discouraged from including general statements here and are encouraged to be as specific as they can in their comments regarding what particular issues may exist. For example, saying the regulatory environment in the U.S. discourages U.S. production is not as helpful to Commerce compared to a specific example of a regulatory provision where the commenter provides a specific example of how that deters U.S. production in their example.
6. Briefly describe your assessment of what the U.S. government is doing or could do to foster private and public sector investment and innovation in the United States in this U.S. PHIB, including investments in upgrades to equipment, or to adopt new, emerging technologies, and/or automation that would increase productivity and competitiveness. Should the U.S. government do more to foster U.S. PHIB investment, particularly in automation, and other emerging technologies? If so, what policy actions should it undertake?
7. With respect to the U.S. PHIB, what are the challenges to investing in automation and other productivity enhancing technologies in the United States compared to moving operations abroad to lower-cost labor countries? How would more efficient and cost-effective automation and productivity enhancing technologies affect your decisions to source all or some of your Essential Medicines, Medical Countermeasures, and Critical Inputs supply chain in the United States?
8. Briefly describe your assessment of whether the amount of federal funds spent on U.S. PHIB R&D is adequate; if not, specify why spending should be increased or decreased. Which types of R&D projects, if adequately funded, would have the most impact on the competitiveness of the PHIB supply chain?
9. Briefly describe your assessment of U.S. Federal procurement policy with respect to the U.S. PHIB and how it encourages and/or discourages investment in PHIB. What, if any, changes would you recommend to U.S. Federal procurement policy to make the PHIB

more productive and internationally competitive and to encourage investment in automation and other emerging technologies?

10. What are the workforce challenges to strengthening the U.S. PHIB, and what are best practices or suggestions for how U.S. industry could overcome these challenges? What have you done to address these challenges? How might emerging technologies in the PHIB create new workforce training needs and which skillsets will the job market most demand?
11. How can the U.S. Government or the private sector help to accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs?
12. In your opinion, what are the three most important things that can be done by the U.S. Government or the private sector to ensure long-term demand for Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States?
13. In your opinion, what are the three most important things that can be done by the U.S. Government or the private sector to create, maintain, and maximize domestic production capabilities for Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense?
14. How great of a problem do you believe is trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third party online sellers involved in the government procurement process? In responding to this question, commenters are encouraged to provide specific examples of how this may have undermined production in the U.S., endangered U.S. citizens, or undermined the reliability of the U.S. supply chain.
15. How great of a threat is cybercrime or malicious cyber activity to your organization and other organizations that you depend on for your supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs? In addressing this question, commenters are encouraged to provide specific examples of how cyber threats such as ransomware, distributed denial of service attacks (DDoS), or malware have undermined production in the U.S. and the reliability of U.S. supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs. How can the U.S. Government or the private sector strengthen the PHIB sector's ability to prevent, detect, and recover from malicious cyber activity? In addressing this question, to what extent, if any, does dependence on foreign suppliers increase your organization's exposure to cybercrime or create any additional burdens because of the complexities involved with dealing with different countries' laws on cyber issues.
16. How dependent is the U.S. sewn products supply chain for use in Personal Protective Equipment (PPE) on foreign suppliers from your organization's perspective? In addressing this question, are there specific factors that undermine U.S. competitiveness in this area of the supply chain and what recommendations does your organization have for

reducing foreign dependency and increasing U.S. competitiveness? In addressing this question, specify whether your organization produces, sells or uses this type of PPE.

DESCRIPTION OF RESPONDENTS: Organizations and individuals involved in the development, production, sale, distribution and use of Essential Medicines, Medical Countermeasures, and Critical Inputs under the U.S. Public Health Industrial Base (PHIB).

TYPE OF COLLECTION: (Check one)

- Customer Comment Card/Complaint Form Customer Satisfaction Survey
 Usability Testing (e.g., Website or Software) Small Discussion Group
 Focus Group Other: Public comments in response to published notice with the public using www.regulations.gov to submit comments in response to the notice.

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Mark Crace

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? Yes No
2. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? Yes No
3. If Yes, has an up-to-date System of Records Notice (SORN) been published? Yes No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes No

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden Hours
Non-Profits, State, and Local	110	120 minutes	220
Totals	110		220

FEDERAL COST: The estimated annual cost to the Federal government is \$339.00. This cost is based on a GS 13 taking 5 minutes to review each submission at a cost of \$37.00 per hour.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[] Yes [x] No

The survey questions will be included in a published notice of inquiry requesting comments from the interested public. Any member of the public may respond to the notice, but Commerce anticipates that only those organizations and individuals involved in the development, production, sale, distribution and use of Essential Medicines, Medical Countermeasures, and Critical Inputs under the U.S. Public Health Industrial Base (PHIB) will be likely to submit comments in response to the published notice soliciting comments.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

[] Web-based survey
(on BIS' public webpage – link provided below)

[] Telephone

[] In-person

[] Mail

[x] Other, Explain. The published notice will direct commenters to use www.regulations.gov to provide comments in response to these survey questions included in the published notice. Commenters will submit their comments using the regulations.gov docket number associated with this published notice.

2. Will interviewers or facilitators be used? [] Yes [X] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

All instruments used to collect information must include:

OMB Control No. 0690-0030

Expiration Date: 07/31/2023