ASPR Industrial Base Management and Supply Chain
Request for Information (RFI)

THIS IS NOT A REQUEST FOR PROPOSALS (RFP) OR A REQUEST FOR QUOTATIONS (RFQ); IT IS STRICTLY A REQUEST FOR INFORMATION (RFI). NEITHER UNSOLICITED PROPOSALS NOR ANY OTHER KINDS OF OFFERS WILL BE CONSIDERED IN RESPONSE TO THIS RFI

TITLE

Public Health Industrial Base Capabilities and Capacities: Essential Medicines

REQUEST FOR INFORMATION (RFI) ONLY

As set forth in FAR 15.201(e), the intent of this RFI is to gather market research on the domestic production capability and capacity of the Public Health Industrial Base (PHIB) as it relates to the list of essential medicines identified pursuant to section 3(c) of Executive Order 13944 of August 6, 2020. This RFI is requesting data and information that would ensure HHS/ASPR's Center for Industrial Base Management and Supply Chain (ASPR-IBMSC) better understands the PHIB capabilities and capacities used to produce and supply drug and biologic essential medicines identified, as of the date of Presidential Determination 2024-03 of December 27, 2023, pursuant to section (c) of Executive Order 13944 of August 6, 2020, and Executive Order 14293 of May 5, 2025.

This RFI is not a solicitation, nor is it a request for competitive proposals, and nor does it commit the HHS ASPR IBMSC Program to issue a solicitation or make an award. Therefore, responses to this notice are not considered offers and cannot be accepted by the United States Government (USG) to form a binding contract. Companies that respond will not be paid for submitting information or administrative costs incurred in response to this RFI. All costs associated with responding to this RFI will be solely at the interested party's expense. The USG intends to utilize the information gathered from this market research effort for planning purposes.

All responsible sources may submit information in response to this RFI.

Please note: Individual responses will be treated as confidential trade secrets or commercial information, consistent with section 552(b)(4) of Title 5, U.S.C., section 1905 of Title 18, and other applicable laws. Such data are exempt from FOIA requests. Data will be marked as business proprietary information, for official government use only and not to be distributed outside of the government.

REQUEST DETAILS:

1. Description

ASPR-IBMSC invites industry partners to submit to the USG information that will aid in improving the understanding of current domestic production capabilities and capacities of domestic PHIB that specifically support the production and supply of essential medicines. Industry responses to the RFI are intended to assist the USG with planning and market research.

2. Background

Within the Federal Government, within the Department of Health and Human Services' Administration for Strategic Preparedness and Response, the Center for Industrial Base Management and Supply Chain aims to build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capabilities by investing in industrial base expansion to further enable ASPR to prepare for, respond to, and recover from both current and future public health emergencies. IBMSC is advancing the ReShoreRx initiative to build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capabilities.

This RFI seeks widest possible dissemination and feedback from industry professionals and those

that develop, produce, and supply essential medicines in the domestic PHIB. The goals are to meet and exceed the growing market demands in the domestic PHIB and to develop and consider a wide array of potential courses of actions and solutions to ensure preservation of health resources considered essential to national defense, including but not limited to the list of essential medicines identified pursuant to section 3(c) of Executive Order 13944 of August 6, 2020.

3. Project Scope

ASPR-IBMSC's intention is to generate market research to better understand the current domestic landscape that can support the production and supply of the precursors, key starting materials, intermediates, active pharmaceutical ingredients, and/or finished dosage forms relevant to the list of medicines provided in section 4 below. ASPR-IBMSC is interested in submissions from entities that either have the capability to provide population-scale solutions or possess technology(ies) that can be rapidly scaled to support population-scale requirements.

4. Requested Information:

In addition to any market research that the respondent deems relevant to the RFI response, HHS ASPR-IBMSC is requesting responses to the following questions:

A. **Technical Questions:**

Please focus all responses on your company's ability to produce and supply the precursors, key starting materials (KSMs), intermediates, active pharmaceutical ingredients (APIs), and/or finished dosage products (FDF) relevant to the medicines listed below:

1) Acetaminophen
2) Albuterol
3) Amiodarone
4) Amoxicillin
5) Aspirin
6) Atropine
7) Ceftriaxone
8) Dexamethasone
9) Diphenhydramine
10) Enoxaparin
11) Epinephrine
12) Fentanyl
13) Furosemide
14) Labetalol
15) Levetiracetam
16) Linezolid
17) Lorazepam
18) Metoprolol
19) Morphine
20) Naloxone
21) Nitroglycerin
22) Norepinephrine
23) Ondansetron
24) Piperacillin
25) Propofol
26) Tazobactam
27) Vancomycin
28) Voriconazole

i. For each of the precursors, KSMs, intermediates, APIs, and FDFs being produced by your company, please provide details regarding the following items below:

a. U.S. regulatory holdings (e.g., DMF, NDA, ANDA, BLA) either in possession or being pursued (including expected approval dates). Include in this response any regulatory filing(s) that are not currently active but could be reactivated using existing domestic infrastructure. Please describe how you demonstrate compliance with FDA's quality management requirements including but not limited to 21 CFR Part 820 and ISO 13485.
b. The scale at which your company is (or while be, if regulatory holding(s) is/are being pursued) producing any of the above (i.e., gram, kilogram, metric ton) and the location of each facility producing these materials. Specify whether your facility(ies) can currently or, through additional investment, expand to address more than one medicine listed above. Include in this response the estimated percent market capture for your company's offering(s) for each precursor, KSM, intermediate, API, and FDF. If currently expanding capacities, provide an estimated percent market capture once the capability is on-line.
c. **Manufacturing equipment, manufacturing processes used, and the associated Manufacture Readiness Level (MRL): https://www.dodmrl.com/MRL_Deskbook_2022__20221001_Final.pdf**.
d. List any key equipment, ingredients, or material(s) cited above that is/are sole-sourced, has a long lead time, and/or is/are manufactured outside the United States (OUS). Provide specifics as to what equipment or material(s) are imported from non-domestic sources, including the country(ies) of origin. Provide details for any item(s) that have experienced increased costs or delivery delays due to sourcing OUS.
e. Present operating capacity at relevant facilities (warm-base, typical monthly output, and surge (100%) capacity). Be specific about population-scale capabilities and if not currently capable of supporting population-scale requirement, describe the required level of investment and associated timeline to reach population-scale manufacturing. Include in this response where technology transfer(s) can be leveraged as a means of expediting time to commencement of domestic production and include details describing the necessary budget and timeline for each tech transfer.

ii. List any existing facility(ies) that can be modernized or repurposed, or where idle capacity exists that can be utilized, to address the manufacturing need for additional medicine(s) from the list above. Be specific about requirements, cost estimates for Capex, and timelines to reach operability. Include projected total cash flow and net cash flow to illustrate the timeline to self-sustainment.

iii. Describe the flexibility of your manufacturing operations. Can your facilities easily adapt to produce different medicines from the list or scale production up or down based on demand? How long does it take to transition your facility(ies) from one product to another? If a multiproduct facility, how many products can be manufactured at the same time (i.e. how many independent manufacturing lines/suites are in your facility). Provide examples if possible.

iv. Provide a list of both existing customer base and prospective customers that sustains your current manufacturing capacity. For prospective customers, please provide the specific product(s) that the customer will procure as well as a summary of progress made towards becoming an Approved Supplier. Include specific documentation that is in-process and approved (e.g., Letter of Intent, Master Service Agreement, Quality Agreement, purchase commitment, purchase order, etc.).

v. Provide details regarding any forecast concerns or other challenges that may impact your ability to maintain current manufacturing capabilities for a period of at least 7 years and any additional domestic capacities.

B. General Questions
   i. What challenges do you foresee with executing the scope of work as described above and what solution(s) have you identified that may mitigate these identified challenges? Please provide any specific regulatory barriers you anticipate in scaling up domestic production and include timeframes necessary for reaching expanded population scale domestic production.
   What can the U.S. Government do to better support industry in ensuring that any reshoring efforts are sustainable long-term?

Individual responses will be treated as confidential trade secrets or commercial information, consistent with section 552(b)(4) of Title 5, U.S.C., section 1905 of Title 18, and other applicable laws. Such data are exempt from FOIA requests. Data will be marked as business proprietary information, for official government use only, and not to be distributed outside of the government.

FORMAT AND PAGE LIMITATION:

RFI responses shall adhere to the following:

- 8.5 by 11-inch paper in a format compatible with either the Microsoft Office software package or Adobe Acrobat
- Limited to a maximum of 30 single-sided, double-spaced pages
- Font for text should be Times New Roman 12-point or larger.
- Numbered pages
- Microsoft Word or Adobe Acrobat format

Existing commercial documentation, technical specifications, and product literature can also be submitted and are not subject to a page limitation.

*** Responses must be marked UNCLASSIFIED ***
Proprietary information provided must be marked appropriately

To protect proprietary information, each line or paragraph on the pages containing such data must be specifically identified and marked with a legend similar to the following:

"*The following contains proprietary information that (name of Responder) requests are not released to persons outside the Government, except for the purposes of review and evaluation.*"

Please note that non-federal ASPR-IBMSC staff performing advisory and assistance services will have access to submissions received under this RFI. All non-federal ASPR-IBMSC staff are required to sign a non-disclosure agreement prior to accessing the RFI responses.

All RFI submissions will become USG property and will not be returned.

Responses must be submitted in the following format:

E-mail Subject Line: RFI No/ Domestic Public Health Industrial Base Capabilities and Capacities: Essential Medicines

PART I: Business Information

Provide the following business information for your company/institution:

- Company/Institute Name:
- Address:
- SAM UIE/DUNS

- Point of Contact:
- Phone Number:
- E-mail Address:
- Web Page URL:
- (**If applicable**) North American Industry Classification System (NAICS) Codes to be provided by Industry.

PART II: Optional Supplementary Information for Consideration by U.S. Government

In addition to the above requested information, use this space to provide any other information you wish the USG to consider as it assesses the health of the market and industry, recommendations you may have for reducing industry vulnerabilities, your view of the marketplace and global competitive playing field, what you believe would level the playing field for domestic manufacturers, or any thoughts on how to increase the long-term health and viability of the industry.

INFORMATION APPROACH:

ASPR-IBMSC may or may not use any of the information provided by industry as the basis for a future project. Projects developed from information provided by industry, as with all ASPR-IBMSC projects, may be competed in the open market using full and open competition. ASPR-IBMSC is not required to provide feedback to responders. However, USG may respond directly in order to obtain additional or clarifying information.

DISCLAIMERS (if any):

No telephone calls will be accepted requesting a bid package or solicitation. There is no bid package or solicitation currently. All RFI submission information received shall be safeguarded from unauthorized disclosure. Responses to this RFI may constitute proprietary information, Controlled Unclassified Information (CUI), or export-controlled information. Respondents are directed to contact the Contracting Office POCs for supplemental instructions related to the submission of proprietary information, CUI, or export-controlled data. If late information is received, it may be considered by the USG reviewers, depending on agency time constraints.

OPERATIONS SECURITY (OPSEC) REQUIREMENTS

All responses to this document shall follow appropriate OPSEC measures. This is required to reduce program vulnerability from successful adversary collection of possible sensitive unclassified and/or proprietary information, and violations of export control requirements. Guidance can be provided by HHS ASPR Security as needed. Please note, any potential critical program information (CPI) generated as part of this response will be reviewed to determine the need for a Program Protection Plan (PPP) or to be included as part of an existing PPP.

INDUSTRY CLARIFICATIONS/DISCUSSIONS

Interested vendors may request clarification regarding the RFI in writing from the Contracting Office for any requirement that is unclear by sending an e-mail to the Contracting Point of Contact: Lori Fischer at lori.fischer@hhs.gov and Roger Henriquez at roger.henriquez@hhs.gov and also submit your response at the main email account at IBMSC-Submissions@hhs.gov.

Any requests for clarification must be received no later than 5 P.M. Eastern Time (ET) on May 16, 2025. The USG may provide clarifying responses that will be posted via SAM.gov website to benefit all interested RFI responders. Interested responders are encouraged to periodically check the website during the response period for updates.

ASPR-IBMSC representatives may or may not choose to respond or meet with potential responders. Such discussions would only be intended to obtain additional or clarifying information. ASPR-IBMSC is not required to provide feedback to responders.

Submission of documentation

ASPR-IBMSC intends to use electronic mail for all correspondence regarding this RFI. Electronic responses to this RFI are due no later than 5 P.M. ET on June 16, 2025.

Documentation shall be submitted to the following individual the Contracting Point of Contact: Lori Fischer at lori.fischer@hhs.gov and Roger Henriquez at roger.henriquez@hhs.gov and also submit your response at the main email account at IBMSC-Submissions@hhs.gov.

Please include RFI No./Title in the subject line of the email and all correspondence concerning this RFI.