Sources Sought Notice

SSN No.: 2-PAM-BARDA-2022
2-PAM Autoinjectors

I. INTRODUCTION

The purpose of this Sources Sought Notice (2-PAM Autoinjectors) is to seek declarations of technical capabilities, data, and materials from qualified other than small business concerns as well as small business concerns relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. The NAICS for this requirement is 541714 (Research and Development in Biotechnology (except Nanobiotechnology)).

THIS NOTICE IS STRICTLY FOR MARKET RESEARCH.

II. AUTHORITY

The Office of Contracts, Management and Acquisition (CMA) issues this Sources Sought Notice (SSN) on behalf of the Biomedical Advanced Research and Development Authority (BARDA) pursuant to FAR paragraphs 5.205(c), 15.201(e) and FAR parts 10, 19.

III. ACRONYM

"AChE" means Acetylcholine Esterase
"CMA" means Contracts Management and Acquisition
"ASPR" means Assistant Secretary for Preparedness and Response
"BARDA" means Office of the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services
"CBRN" means Chemical, Biological, Radiological, and Nuclear
"DUNS" means data universal numbering system
"FAR" means Federal Acquisition Regulation
"FDA" means the U.S. Food and Drug Administration
"HHS" means the U.S. Department of Health and Human Services
"HSPD" means Homeland Security Presidential Directive
"HUB Zone" means Historically Underutilized Business Zone
"Licensed" means approved for use by a regulatory authority,
"MCM" means Medical Countermeasure
"NAICS" means North American Industrial Classification System
"NHSS" means National Health Security Strategy
"NMS-CWMD" means National Military Strategy to Combat Weapons of Mass Destruction
"Notice" means this Sources Sought Notice
"NSPD" means National Security Presidential Directive
"OP" means organophosphate
"OTSBSSN" means Other Than Small Business Sources Sought Notice
"2-PAM" means Pralidoxime; 2-pyridine aldoxime methyl chloride
"PHEMCE" means the Public Health Emergency Medical Countermeasures Enterprise
"SB" means Small Business
"SDB" means small disadvantaged businesses
"SDVOSB" means service-disabled veteran-owned small businesses

"SNS" means Strategic National Stockpile
"SSN" means Sources Sought Notice
"VOSB" means veteran-owned small businesses
"WOSB" means women-owned small businesses

IV. PURPOSE

The Office of the Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) intends to use responses to this Sources Sought Notice (SSN) for planning potential future acquisitions. BARDA seeks pertinent marketplace data on availabilities and capabilities for procuring, stockpiling, and investing in the late-stage development of Pralidoxime (2-pyridine aldoxime methyl chloride; 2-PAM) autoinjectors for intramuscular injection. BARDA seeks information on availability, capabilities, and other pertinent marketplace data to support late-stage activities required for Food and Drug Administration (FDA) approval of 2-PAM (600 mg) autoinjectors. This information is intended to strengthen BARDA's understanding of the current and future marketplace and enhance its ability to obtain quality services economically and efficiently, and to lawfully establish potential vendor source files and listings. BARDA will not award any contracts under this Notice.

V. BACKGROUND

The Office of the Biomedical Advanced Research and Development Authority intends to use responses to this SSN for planning purposes towards the possible procurement of 2-PAM autoinjectors designed for use by adult and pediatric populations for the treatment of organophosphate (OP) poisoning, including nerve agents.

Within the Federal Government, the U.S. Department of Health and Human Services (HHS) is tasked with protecting the civilian population by providing leadership in research, development, acquisition, deployment, and use of effective Medical Countermeasures (MCMs) to treat the adverse health effects resulting from intentional release leading to exposure to chemical, biological, radiological, and nuclear (CBRN) threat agents, pandemics, and emerging infectious diseases. Response and recovery were identified as key elements of national defense in the National Strategy to Combat Weapons of Mass Destruction issued in 2002 (National Security Presidential Directive-17/Homeland Security Presidential Directive-4, NSPD-17/HSPD-4) and in the National Military Strategy to Combat Weapons of Mass Destruction (NMS-CWMD), released in 2006. This procurement is also aligned with the Project Bioshield Act of 2004 (Pub. L. No. 108-276, www.gpo.gov/fdsys/pkg/PLAW-108publ276/pdf/PLAW-108publ276.pdf), which established the processes by which MCMs are procured for the Strategic National Stockpile (SNS).The lead role of HHS in the medical and public health response, including development and availability of MCMs, was emphasized in 2004 in Biodefense for the 21st Century (HSPD-10) and in 2007 in Medical Countermeasures against Weapons of Mass Destruction (HSPD-18). The importance of an effective MCM enterprise for development and provision of medical countermeasures was emphasized in the National Health Security Strategy (NHSS, first published in 2009 and updated most recently in 2019 https://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx). These documents represent the foundation for addressing the Nation's CBRN MCM needs.

Development of 2-PAM Autoinjectors for Treatment of Organophosphorus (OP) Poisonings, Including Nerve Agents

Organophosphate or nerve agent poisoning requires intervention to occur quickly given the rapid onset of symptoms, which manifest within minutes, rather than hours. Pralidoxime (2-PAM) and atropine, an anticholinergic, must be administered as soon as possible. Both drugs should be available as far forward as practical, in a presentation that allows for ease of use in a mass casualty scenario. Intramuscular autoinjectors fulfil this requirement. Modern, FDA-approved, atropine autoinjectors are available, but there are currently no 2-PAM autoinjectors aside from those found in MARK-1™ kits, a legacy set of nerve-agent countermeasure autoinjectors currently stocked by the Strategic National Stockpile (SNS) under the Shelf Life Extension Program. There is a requirement for SNS to stockpile a modern acetylcholinesterase reactivator (2-PAM, 600 mg) to complement existing atropine autoinjectors. These new 2-PAM (600 mg) autoinjectors would replace those held in the legacy Mark-1 kits. The military has moved toward use of a dual drug autoinjector (ATNAA/DuoDote®) that includes both atropine (2.1 mg) and 2-PAM (600 mg); however, this product may soon be discontinued by the manufacturer. PHEMCE has determined that the needs of the SNS in treating a diverse civilian population would be better served by the flexibility of separate autoinjectors for the two drugs. Therefore, development and acquisition of 2-PAM (600mg) IM autoinjectors and their approval as a drug/device combination product for the treatment of organophosphate and nerve agent poisonings will fulfill the present requirement.

VI. PROJECT REQUIREMENTS

This notice seeks information from Other than Small Businesses (OTSB) and Small Businesses (SB) regarding their qualifications, experience and capability to develop and manufacture emergency 2-PAM autoinjectors.

Any proposed therapeutic and Sponsor must meet the following criteria:

- The Offeror must have the capability to manufacture 2-PAM (600 mg) autoinjectors that are FDA approved or in late-stage development with the ability to achieve full FDA approval by end of 2025.

- The Offeror must demonstrate that their proposed autoinjectors will be able to meet the FDA reliability standard for emergency use autoinjectors (99.999% reliability, see https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda) by the end of 2024. Offeror must provide a high-level plan to support their timeline; *Design for Six-Sigma* methodologies are preferred for new products. The Offeror must have obtained FDA feedback regarding their regulatory approach. The feedback or a summary in should be included in the response to this Notice.

- The Offeror must have demonstrated their autoinjectors can be used in emergency situations by first responders and untrained personnel (Human Factors Studies are acceptable).

- The Offeror must have demonstrated capability to manufacture and deliver 2,000,000 of 600 mg 2-PAM autoinjectors in 500,000 increments to the SNS by September 30, 2029. Please include average production rate and surge capabilities.

Proposed capability should include the ability to deliver 2-PAM autoinjectors, as a drug/device combination product, to the SNS for supplementation to CHEMPACKS.

VII. CAPABILITY STATEMENT/INFORMATION SOUGHT

Respondents are asked to provide only the most pertinent information, data, and materials necessary to adequately convey a declaration of capability in line with this notice. Respondents must submit separate Business and Technical Representation (detailed in Sections 1-4 below), and each shall each not exceed 10 single sided pages (including all attachments, resumes, charts, etc.) in 12pt Times New Roman font. Content contained in excess of the stated limit per section will not be reviewed. Respondents are asked to state in their capability statement, whether they are a Small Business or Other than Small Business concern.

1. Business Representations

Respondents must make business representations to ASPR/BARDA in the following order:

a) Business Information

Provide potential respondent name, principal place of business, DUNS number, taxpayer identification number, number of employees, annual revenue of company, point of contact, and email address.

b) NAICS Codes

Provide your applicable NAICS Code.

c) Compliance Statement

Provide a statement assuring compliance with all applicable laws and this Notice.

d) Capability Statement

Provide relevant business information on capability, prior experience, and business interests to provide the type of good and services specified under Section VI, above.

2. Technical Representations

Respondents shall make the technical representations to ASPR/BARDA in the order listed below as separate sections. (Note: sections not relevant to the respondent may be left without information by marking it 'NA/Reserved,' to maintain the section numbering).

a) Response Specification

In response to this notice, clearly describe the capability and experience that meets the requirements specified in Section VI.

b) Technical Information:

All sponsors responding to this notice are required to provide the information on their products and capabilities by providing a short narrative and summarizing the stage of development, non-clinical and clinical studies completed to date, stability data, manufacturing accomplishments, and FDA interactions. The short narrative may include figures, schematics, diagrams, photographs, etc. and shall describe the proposed final products under consideration.

Technical Information - Narrative Sections:

1. Product Name: As marketed or published.

2. Intended Indication for use as a therapeutic capable of meeting product requirements outlined in section VI.
3. Regulatory Status or Stage of Development: Provide summaries of communications with the FDA describing current state of medical product development according to the FDA pathways.
4. Clinical Development: Provide a summary of preclinical and clinical development, including summaries of any FDA feedback. The Offeror must clearly demonstrate that their proposed autoinjectors will be able to meet the FDA reliability standard for emergency use autoinjectors (99.999% reliability) by the end of 2024.
5. Current Manufacturing Capacity: Provide a summary of manufacturing achievements, completed manufacturing runs, and manufacturing capacity.
6. Shelf Life and Storage Conditions: Provide a summary of stability and storage as measured by time and temperature.

3. Other Information
ASPR/BARDA encourages respondents to submit currently available marketing or extant information, or to notify ASPR/BARDA of the publicly available location thereof to the maximum extent consistent with this notice's requirements and limitations.

4. Response Format, Transmission, and Closing Date
Respondents shall provide declarations of capability and all information, data, and materials in Microsoft Office®, or Adobe® Acrobat® format, and furnish responses electronically (via email) to jennifer.taranto@hhs.gov **for receipt by 4:00 P.M. ET on February 7, 2022.** Any questions, comments, or concerns regarding this notice shall be written and transmitted via email to jennifer.taranto@hhs.gov.

VIII. DISCLAIMER AND IMPORTANT NOTES

This notice is issued solely for information and planning purposes and does not obligate the Government to award a contract. No entitlement to payment of direct or indirect costs or charges by the Government will arise as a result of the submission of the requested information. No reimbursement will be made for any costs associated with providing information in response to this announcement and any follow up information requests. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published on SAM.gov under Contract Opportunities in accordance with FAR part 5. However, responses to this notice will not be considered adequate responses to a solicitation.

IX. CONFIDENTIALITY

Respondents shall mark confidential, privileged, proprietary, trade-secret, copyrighted information, data, and materials with appropriate restrictive legends. ASPR/BARDA will presume that any unmarked information, data, and materials were furnished with an "unlimited rights" license, as FAR subpart 27.4 defines that term, and ASPR/BARDA assumes no liability for the disclosure, use, or reproduction of the

information, data, and materials. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation.