Sources Sought Notice

Title: Advanced Dermal Regeneration Substitutes for Treatment of Severe Burns and Complex Traumatic Injuries
Special Notice No.: BARDA-CBRN-07282026

I. PURPOSE

The Biomedical Advanced Research and Development Authority (BARDA) intends to use responses to this Sources Sought Notice (SSN) for planning purposes. BARDA will not award any contracts under this Notice, but rather seeks current and forecasted prices, inventories, capabilities, and other pertinent marketplace data.

This Notice is issued by the Biomedical Advanced Research and Development Authority (BARDA) to identify innovative medical countermeasure technologies capable of addressing large-area skin loss due to thermal burns or traumatic injuries in a mass casualty incident. This request is for information only and is intended to assess the current state of commercially available or near-commercial availability technologies that support temporizing wound healing, accelerated wound closure, infection control, and functional tissue regeneration.

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. Information collected in response to this SSN will enhance BARDA's ability to establish potential vendor source files and listings and lawfully execute the preparedness mission efficiently and lawfully.

III. 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 a vendor managed inventory of advanced dermal regeneration substitutes for treatment of severe burns and complex traumatic injuries.

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), 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). These documents represent the foundation for addressing the Nation's CBRN MCM needs.

Severe burns and complex traumatic injuries resulting from blast explosions, radiation exposure, or chemical incidents present significant challenges in both civilian and emergency response settings. Current standards of care are limited by complex supply chains, donor site availability, risk of infection, delayed healing, and suboptimal functional and cosmetic outcomes. BARDA is seeking potentially two candidate products that enhance the body's ability to regenerate dermal tissue, reduce reliance on autografting, and improve patient outcomes in both routine and surge scenarios for full-thickness burns and traumatic wounds where skin and tissue loss are a major injury.

IV. CAPABILITY STATEMENT/INFORMATION SOUGHT

This notice seeks information from Other than Small Businesses (OTSB) and Small Businesses (SB) regarding their qualifications, experience and capability to develop, manufacture and store advanced dermal regenerative dermal substitutes

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 Technical Representation and Business (detailed in Sections 1-4 below) and shall 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. 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 criteria specified in the subsequent categories. A template is provided for detailed and concise responses as related to the qualifying criteria. Additional supporting evidence, data, and information can be provided as attachments, not to exceed the 10 pages limit per submission to this notice.

Any proposed device and sponsor must qualify the following criteria:

1. **Dermal Regeneration Capability**
    - Supports formation of vascularized neodermis
    - Enables integration with host tissue and subsequent epithelialization
    - Suitable for full-thickness burns, complex traumatic wounds, and large surface area injuries
2. **Infection Control and Barrier Function**
    - Provides an effective barrier to microbial infiltration
    - Demonstrates reduced infection rates compared to standard of care
    - May incorporate antimicrobial or biofilm-resistant properties
3. **Use-Case Flexibility**
    - Ready-to-use or minimal preparation required at point of care
    - Stable under a range of storage conditions (ambient required)
    - Long shelf life suitable for stockpiling
4. **Scalability and Manufacturing**
    - Has US domestic manufacturing capabilities
    - Manufactured using reproducible, scalable processes
    - Not dependent on human or animal donor tissue

- Capable of rapid production scale-up in emergency scenarios

5. **Ease of Use in Diverse Settings**
   - Applicable in austere, field, or resource-constrained environments
   - Does not require highly specialized surgical expertise
   - Compatible with existing burn care workflows and continuum of care
6. **Clinical and Regulatory Maturity**
   - Evidence of clinical safety and efficacy (human data preferred)
   - Regulatory status (e.g., cleared, approved, or late-stage development)
   - Established or plausible reimbursement pathway
7. **Composition of Product**
   - Fully Synthetic construct
   - Biosynthetic composite
   - Acellular/cellular dermal substitute
8. **Storage Requirements**
   - Stable at ambient temperature (20–25°C) without refrigeration
   - Long shelf life suitable for strategic stockpiling (minimum 2–5 years preferred)
   - Does not require cold chain logistics
   - Minimal storage footprint and ease of inventory management
9. **Indicated Population**
   - Broad applicability across adult and pediatric patient populations
   - Applicable to traumatic wounds, blast injuries, and soft tissue defects
   - Demonstrated safety and efficacy across a range of wound sizes and body locations
10. **Scalability of Treatment**
    - Minimizes the number of treatment applications or replacement procedures
    - Extends the period available for managing complex, traumatic, or burn wounds
    - Enables efficient use of healthcare personnel and treatment capacity
11. **Rapid Deployment and Distribution**
    - Established distribution network capable of national and international delivery
    - Rapid order-to-delivery timelines during routine and surge operations
    - Scalable logistics infrastructure capable of supporting large-scale deployment
    - Supply chain resilience with multiple manufacturing and distribution pathways
12. **Supporting Documentation and Evidence**
    - Peer-reviewed clinical evidence supporting safety and effectiveness
    - Regulatory documentation demonstrating current approval, clearance, or development status
    - Product Instructions for Use (IFU) and training materials available
    - Manufacturing and quality system documentation
    - Stability and shelf-life data supporting storage claims
    - Supply chain and production capacity information available
    - Health economic, reimbursement, or cost-effectiveness data available

b) Technical Information

All sponsors responding to this notice are required to provide the requested information on their products and capabilities by providing short responses, summarizing their product's dermal regeneration capability along with clinical data, regulatory documentation, product IFU, manufacturing overview, supply-chain and production information. The narrative response to the templated prompts may include figures, schematics, diagrams, photographs, etc. and shall describe the proposed final products under consideration.

2. Business Representations

The business narrative shall cover company information, including capability to supply the product. This includes the following:

a) Company mission and description of the business information (registered as small business/NAICS code), including locations, management, and employees.

b) Organizational capability across the US for management of product manufacturing, supply chain, raw materials, warehousing, inventory management, distribution, and surge capacity.

c) If serving as a commercial distributor, commercial distribution rights, limitations, and risk mitigation of supply chain.

d) Provide current market list price. To the extent possible provide future market projections and market share as a percentage of the total market.

e) Summarize any plans and strategy to increase product penetration into the U.S. burn and trauma injury market.

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 Yifan.Yang@hhs.gov for receipt by 4:00 PM ET on August 28, 2026. Any questions, comments, or concerns regarding this notice shall be transmitted via email to Yifan.Yang@hhs.gov.

V. 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.

VI. 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.