Request For Information (RFI)

Medical Countermeasures for the Treatment of Drug-Resistant Fungal Infections
RFI No. MCM TDRFI: BARDA-2026

PURPOSE

The Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), is issuing this Request for Information (RFI) to collect feedback from current and prospective antifungal development partners. Information obtained from this RFI will serve as continued planning for potential future acquisitions and programs. The information collected in response to this RFI is intended to strengthen BARDA's understanding of the current and future marketplace. This notice seeks information from Other than Small Businesses (OTSB) and Small Businesses (SB) regarding their qualifications, experience, and capabilities.

THIS IS STRICTLY FOR PLANNING PURPOSES.

AUTHORITY

The Office of Contract, Management and Acquisition (CMA) is issuing this RFI on behalf of BARDA pursuant to FAR paragraphs 5, 15.101(c) and FAR parts 10, 19. Information collected in response to this RFI will enhance BARDA's ability to establish potential vendor source files and listings as well as lawfully execute the preparedness mission efficiently.

BACKGROUND

Within the Federal Government, ASPR/BARDA is tasked with protecting the civilian population from the adverse health effects resulting from intentional or unintentional release and exposure to Chemical, Biological, Radiological, and Nuclear (CBRN) threat agents, pandemic influenza, and emerging infectious diseases; this includes secondary fungal infections caused by drug-resistant fungi resulting from illness and injuries from these events. Development and procurement of antifungals that overcome known and emerging forms of resistance will enhance the USG's emergency preparedness.

The subject of this Request for Information is to gain information regarding first-in-class antifungals in development for the treatment of drug-resistant *Candida* species, including *Candida auris*, and/or drug-resistant *Aspergillus* species.

DESCRIPTION

BARDA is issuing this RFI to assist in understanding the landscape of antifungals in development for the treatment of invasive fungal infections. For the purpose of this RFI, BARDA is seeking:

- First-in-class small molecule or peptide-based antifungals that are currently in Phase 2 clinical trials or beyond (e.g., including FDA or EMA approved) with an intended treatment and prophylaxis indications or treatment only indication to address drug-resistant invasive fungal infections (e.g., *Candida* spp., including *Candida auris*, and/or *Aspergillus* species). Broad-spectrum candidates that are effective against yeast and molds and that are available as oral and IV are desirable.

Respondents are asked to provide the following information:

1. Overview of the antifungal candidate:
    a. Pathogens targeted
    b. Differentiating from other FDA approved antifungals

c. Clinical indication(s) sought or approval date (if applicable)
d. Commercial formulation (IV, PO)
e. FDA correspondences and future FDA meeting plans
f. Status of the IP
g. Proposed timeline for sNDA or NDA submission

2. Overview of clinical development status:
    a. Phase 1 trial(s)
        i. Trial design and endpoints
        ii. Safety data summary
        iii. Final CSR – date completed and summary of data
    b. Phase 2 trial(s)
        i. Trial design and endpoints summary
        ii. Enrollment target and date completed (or target completion)
        iii. Interim analysis – date completed (or target completion) and summary of data (if available)
        iv. Final CSR – date completed (or target completion) and summary of data (if available)
    c. Phase 3 trial(s)
        i. Trial design and endpoints summary
        ii. Enrollment target and date completed (or target completion)
        iii. Interim analysis – date completed (or target completion) and summary of data (if available)
        iv. Final CSR – date completed (or target completion) and summary of data (if available)
    d. Black Box Warnings or anticipation of a Black Box Warning with a risk-benefit assessment to justify the products use during a public health emergency

3. Overview of nonclinical studies and status:
    a. In vitro and in vivo efficacy
    b. In vitro pharmacology/pharmacodynamics and ADME studies
    c. Toxicology and safety data

4. Manufacturing
    a. Manufacturing process – summary of the current process, status, and plans, with timelines, for drug substance (DS) and drug product (DP) manufacturing
    b. Registration/primary batches – summary of the current status and plans, with timelines
    c. Process validation – summary of current status and plans, with timelines
    d. Stability testing – summary of stability data for drug substance (DS) and drug product (DP) and plans to achieve 5 years of product shelf-life for the DS and DP
    e. Summary of current demonstrated and planned manufacturing scale
    f. Status of contract manufacturing organization (CMO), including location, and whether any US domestic capacity currently exists for both DS and fill/finish of DP. If US domestic capacity does not yet exist, provide a timeline and summary of the approach to onshore both DS manufacturing and fill finish of DP

5. Procurement:
    a. If procured, the USG-owned product must be able to be 1) delivered as final drug product (FDP) to the ASPR/SNS or; 2) maintained as FDP by the sponsor as vendor managed inventory (VMI). Provide a summary of how the Respondent would meet both of these requirements should BARDA procure the antifungal for stockpiling.

6. Commercialization
    a. Summary of the current or planned commercial development strategy for the candidate and a corporate sustainability strategy
    b. Provide a Target Product Profile (TPP)

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. Responses should be limited to 12 single sided pages or less. Content more than the stated limit per section will not be reviewed. Respondents are asked to state in their response whether they are registered as a small business. Responses shall be sent electronically to Audrey.Glover@hhs.gov and Jonathan.Gonzalez@hhs.gov **for receipt by 5 P.M. EST on 6/21/2026**. Any questions, comments, or concerns regarding this notice shall be sent to Audrey.Glover@hhs.gov and Jonathan.Gonzalez@hhs.gov.

DISCLAIMER AND IMPORTANT NOTES

This notice is issued solely for information and planning purposes and does not obligate the US Government to award a contract. No entitlement to payment of direct or indirect costs or charges by the US Government will arise because 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 US 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 US Government to determine the organization's qualifications to perform the work. Respondents are advised that the US 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.

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.