



FY25 FDA Broad Agency Announcement (BAA) Question & Answer Session

BAA Team

Office of Regulatory and Emerging Science (ORES)

Kinnera Chada, Jessika Alfaro, Ruize Li

Office of Acquisitions and Grants Services (OAGS)

Ian Weiss, Craig Wright

January 16, 2025

Agenda



- Updates
- Reminders
- Q & A Session
 - Previously Received Questions
 - Live

Recording of the full event (including closed captioning and an audio transcript), presentation slides, and answers to all questions (received via email to FDABAA mailbox and live) will be posted on [FY25 FDA Broad Agency Announcement Question and Answer Session - 01/16/2025 | FDA](#) by 1/23/2025

FDA BAA Updates



➤ Concept Paper Template Updates

Does the proposal involve DURC, PEPP, and/or nucleic acid synthesis (See Part III, Section 9.1 for details)? Yes or No

All submitted research proposals must be compliant with the United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Policy published in May 2024.

- FDA's recommendations for Optional Early Concept Papers were communicated to applicants on December 16th, 2024. Any feedback received from FDA Program Offices was communicated to the applicants.
- Updated solicitation will be posted on SAM.gov on 1/17/2025

Reminders



Documents	Details
Stage One Package	<p>Freestanding PDF documents for <i>Checklist</i>, <i>Concept Paper</i>, and <i>Full Proposal</i> sent via single email to FDABAA@fda.hhs.gov</p> <p>-SUBMIT recommendation based on Optional Early Concept Papers or New Applications</p>
<i>Checklist</i>	Attachment 3
<i>Concept Paper</i>	Cover Table and Overview; Attachment 4
<i>Full Proposal</i>	Volume I- Technical Proposal; Attachment 5 Volume II- Cost Proposal

Communication Timelines



Due Date	Description
02/24/2025	Stage I package submission due for FY25 funding consideration Submit all required documents for Stage One Package: Checklist, Concept Paper, Full Proposal
03/06/2025	-Application receipt acknowledgement notification -Stage I review initiated for complete applications with SUBMIT recommendation -Review Concept Papers of new applications by FDA Offices for program relevance
04/07/2025	Regret notification for applications not moving forward for Stage I review
14-calendar days	Stage II Revised Full Proposal Submittal Package request from FDA
09/30/2025	Decision notification for applications moving forward for Stage I/II review
2/25/2025-9/20/2025	Rolling Stage I package submission for FY26 funding consideration: Checklist, Concept Paper, Full Proposal
12/01/2025	Decision notification for pending applications moving forward for Stage I/II review

Previously Received Questions

Live Questions



Thank You

