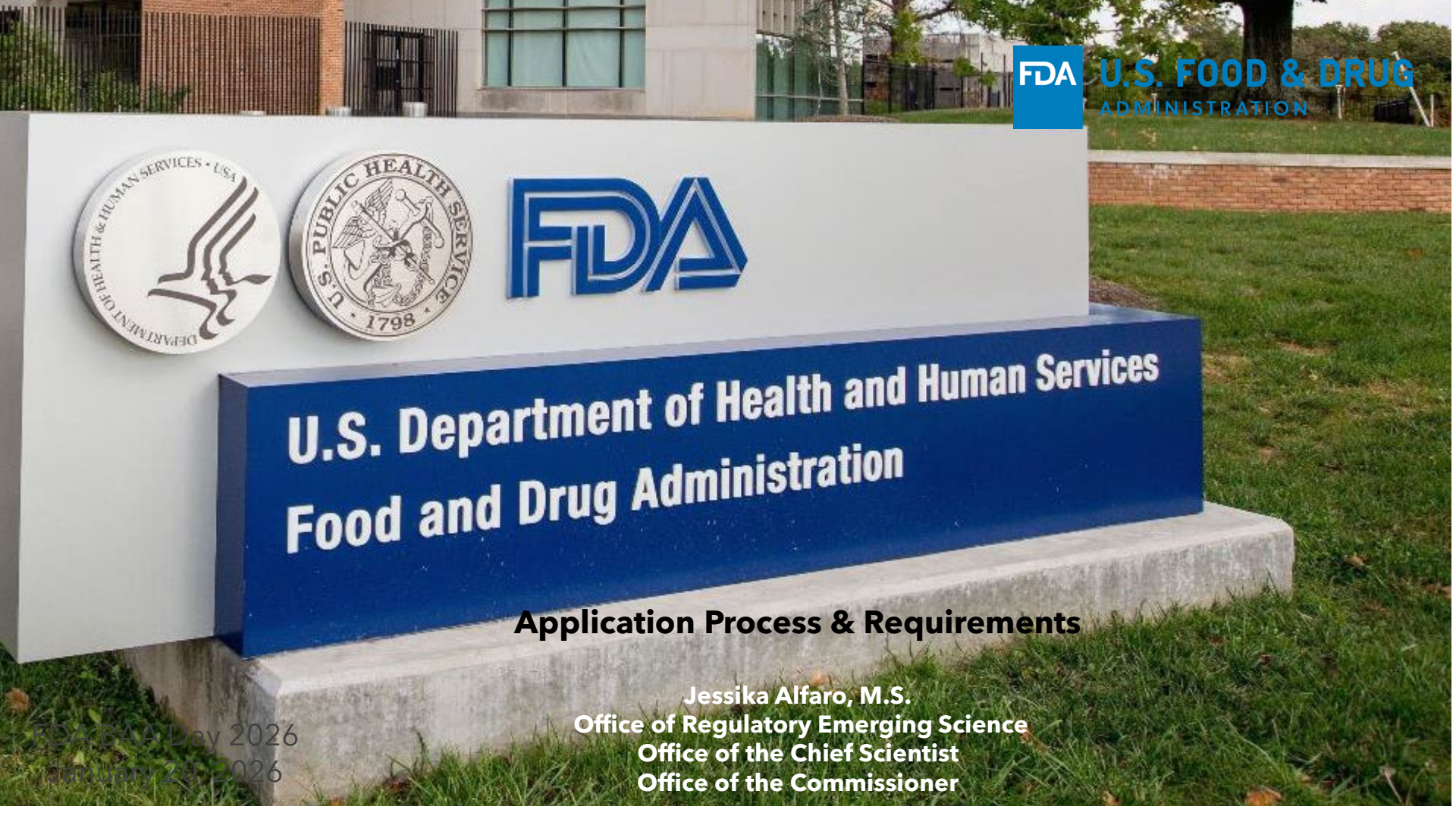


Application Process & Requirements

Jessika Alfaro, M.S.
Office of Regulatory Emerging Science
Office of the Chief Scientist
Office of the Commissioner

FDA BAA Day 2026
January 20, 2026

Presentation Outline

1. BAA proposal submission
2. Proposal Evaluation

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission

- FY26 BAA solicitation version 3 has been posted January 16, 2026, on SAM.gov. (Last amendment posted)
  - Amendments have been highlighted:
  - FY26 BAA solicitation version 2 – amendments highlighted in yellow
  - FY26 BAA solicitation version 3 – amendments highlighted in blue

- Please note that SAM.gov webpage appears with a version log. Please ensure the version in the upper-right corner for the webpage is set to the most recent date.

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission

- This BAA is a continuously open announcement
  - valid throughout issuance date of November 21, 2025, through the closing date of September 21, 2026

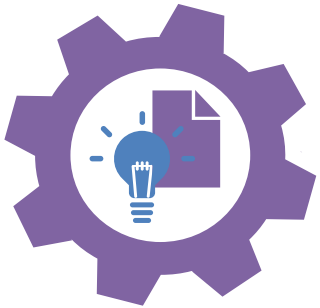
- **Optional Early Concept Paper phase has been removed** from the FY26 FDA BAA Announcement posted on SAM.gov

- For FY26 Funding Consideration Stage I submittal Package shall be submitted no later than **5:00 PM Eastern Standard Time* February 24, 2026.** Early application are highly encouraged
  - *change from November 21, 2025, solicitation posting
  - Stage I submittal Package (see Part III: Proposal Preparation and Submission for further details)

- Stage One Submittal Packages received after 5:01PM EST February 24, 2026, will still be accepted, but due to a lack of lead time and funding availability may not be considered for award in FY26. These submissions may be considered for award in FY27

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

BAA proposal submission Continued



Prospective Offerors are required to submit **Stage One Submittal Packages** with:

1. Checklist following required template (See attachment 3)
2. Freestanding Concept Paper following required template (See attachment 4)
3. Freestanding Full Proposal following required template (see Attachment 5 & Part III for details)

Part III: Proposal Preparation and Submission,
Staring on Pg. 47

Section 1: The application process, Pg. 47
Section 2: Stage 1 Concept paper and Full Proposal, Pg. 49
Section 3: Stage 2 Revised Full Proposal, Pg. 60 **(Need Based Only)**
Section 4 -17 – additional important information, starting on Pg. 60

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

Table 1: Fiscal Year 2026 Priority Regulatory Science Research Areas of Interest								
	FDA-Regulated Areas					Groups & Populations		
Charge	Crosscutting	Biologics	Devices	Drugs	Veterinary	Women	Persons with Rare Diseases	Persons with Cancers
I. Modernize Development and Evaluation of FDA-Regulated Products								
A. New Approach Methodologies	X					X	X	
B. Advanced Manufacturing Approaches	X	X		X				X
C. Analytical and Computational Methods	X	X	X	X	X	X	X	X
D. Biomarkers	X					X	X	X
E. Clinical Outcome Assessment			X			X	X	X
F. Complex and Novel Clinical Trial Design			X	X		X	X	X
G. Predictive Toxicology	X					X		
H. Methods for Assessing Behavioral, Economic, or Human Factors			X	X				
I. Approaches to Incorporate Patient and Consumer Input	X		X					
J. Methods to Assess Real-World Data to serve as Real-World Evidence	X	X		X	X	X	X	X
K. Methods to Assess Data Source Interoperability	X							
II. Strengthen Post-Market Surveillance and Labeling of FDA-Regulated Products								
A. Methods to Assess Real-World Data to Support Regulatory Decision-Making	X		X			X		X
B. Using and Validating Artificial Intelligence Approaches	X		X	X		X		X
C. Novel Clinical Trial Design, Statistical and Epidemiologic Methods	X							X
D. Automated Reporting Tools for Adverse Events and Active Surveillance	X	X		X				X
E. Methods to Improve Communication About Risk to Patients and Consumers						X		
III. Invigorate Public Health Preparedness and Response of the FDA, Patients, and Consumers								
A. Medical Countermeasures	X				X	X		
B. Antimicrobial Resistance				X				
C. Substance Use and Misuse				X		X		
D. Global Product Safety Net	X	X		X	X			
E. Emerging Technologies			X					

REGULATORY SCIENCE FRAMEWORK – (Starting on Pg. 9)

Please specify on your submission & assign the most closely aligned from each areas listed in the FY26 BAA Announcement if your proposal is applicable to more than one

- **Charge Area**
  - (i.e., I. modernize development and evaluation of FDA regulated products)
- **Regulatory Science Topic Area of Interest**
  - (i.e., B. Advanced Manufacturing Approaches)
- **FDA Regulated Areas**
  - (i.e., Crosscutting)

  and/or
- **Groups and Populations**
  - (i.e. persons with cancer)

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

Concept Paper & Concept Paper Overview
(attachment 4)

Concept Paper Cover Table:

Project Title:	
Charge Area:	**Regulatory Science Topic Area of Interest**:
FDA Regulated Areas:	**Groups & Populations**:
Primary Research Area:	**Secondary Research Area**:
Offeror:	**Offeror Contact Information**: **Name-** **Email-** **Phone-**
Principal Investigator:	**Affiliations**:
Research and Development Justification: Broad Agency Announcements, as described in the Federal Acquisition Regulations (FAR), may only be issued for the procurement of Research and Development (R&D). All acquisitions resulting from this announcement must meet one or more of the FAR definitions for basic research (See FAR 2.101(b)(2)), applied research (See FAR 35.001) and development (See FAR 35.001). Include a brief and clear justification describing how the project falls under the FAR requirements for R&D work.	
#Does the proposal involve DURC and/or ,PEPP (See Part III, Section 11.1 for details)? ☐Yes or **☐No**	
Primary Research Area (i.e, II.B.7.e) and **Status** of previous submission (i.e., Recommended for Stage One Package Submission (BAA Number provided- Highlight revised sections), Not Recommended for Stage One Package Submission, Unknown).	

* Included in the 3 pages limit

FY26 FDA Broad Agency Announcement (BAA) for Advanced Research and Development of Regulatory Science

Concept Paper & Concept Paper Overview (attachment 4)

1. **Concept Paper Overview Research Strategy**:
   a. **Aims**: Succinctly list the **specific objectives of the proposed research** (State the problem/objective and

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provide motivation for addressing that problem/objective) and **primary scientific challenges being addressed**

   b. **Methods**: Clearly **describe the approach, description of level of effort, and the nature as well as extent of the anticipated results of the effort** (one Figure that is a 508 compliant picture or graphic that illustrates the research or concept can be included)

   c. **Considerations**: **Brief description of the Offerors intellectual property ownership, data ownership, or licensure; statements on work experience for similar effort with FDA or another agency**

2. **Regulatory Science Impact**
   a. How does this research address an unmet need or fill a critical knowledge gap to advance regulatory science and the program's priorities? How might FDA apply the research findings to the development of new tools, approaches, or standards? Please explain the benefits of proposed technology and challenges and how the proposed project aligns with the objectives of FDA Regulatory Science

3. **Proposed Deliverables and Funding**
   a. List of the major goals, deliverables, or milestones and proposed funding by project year. Total proposed funding is the Base period cost plus each option period with no more than 5 years total.

Milestones	Timeline	Funding
Total Proposed Funding:		

* Included in the 3 pages limit

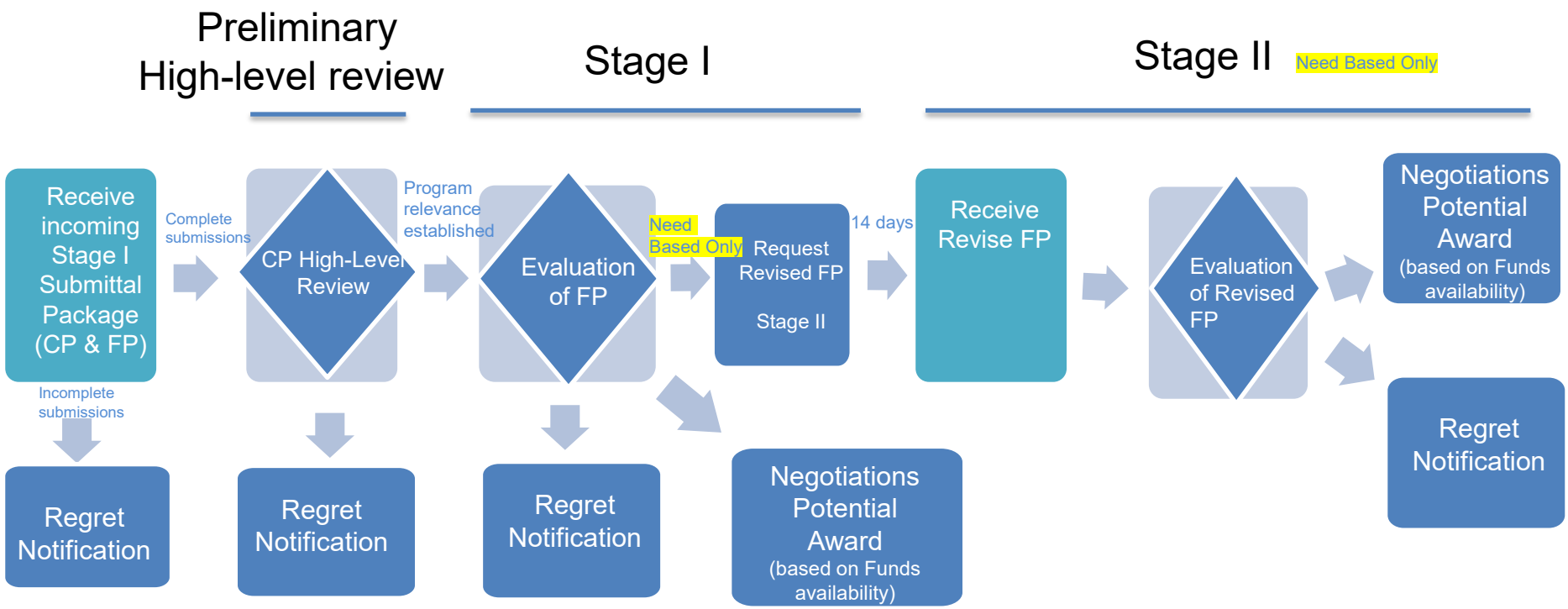
Full Proposal

- Full Proposal expands on the information provided in the freestanding Concept Paper.
- Full Proposal must be prepared as two separate volumes: **Volume I Technical Proposal** and related Appendices and Volume II Cost Proposal and related Appendices.
- Volume I Technical Proposal: See Part III of the solicitation for preparation details
- See Attachment 5 of the FY26 Solicitation for template

	Volume I – Technical Proposal Checklist *section included in 50-page limit ^section included in 30-page limit	
☐	1. Cover page	
☐	2. Official Transmittal Letter	
☐	3. Table of contents	
☐	4. Table of acronyms	
☐	5. *Executive Summary	
☐	6. *Research and Development Justification	
☐	7. *Scientific and Technical Information	
☐	8. *Regulatory Science Impact	
☐	9. *Resources Proposed	
☐	10. *Gantt Chart, Work Breakdown Structure and Milestones	
☐	11. *Deliverable Schedule	
☐	12. *Risk mitigation plan	
☐	13. Security Planning	
☐	14.Intellectual Property	
☐	15. Bibliography/References	
☐	Appendix	
	☐	Biographic sketches (required)
	☐	Security (if applicable)
	☐	Statement of Work (required)
	☐	^Intellectual Property (required)
	☐	^Contractual Agreements (if applicable)
	☐	^Protection of Human Subjects (if applicable)
	☐	^Animal Use (if applicable)
	☐	^Use of Select Agents (if applicable)
	☐	#^DURC, PEPP (If applicable, see Part III, Section 11.1 for details)
	☐	^Regulatory or Compliance Approvals: Laboratory License Requirement (if applicable)

BAA Proposal Evaluation

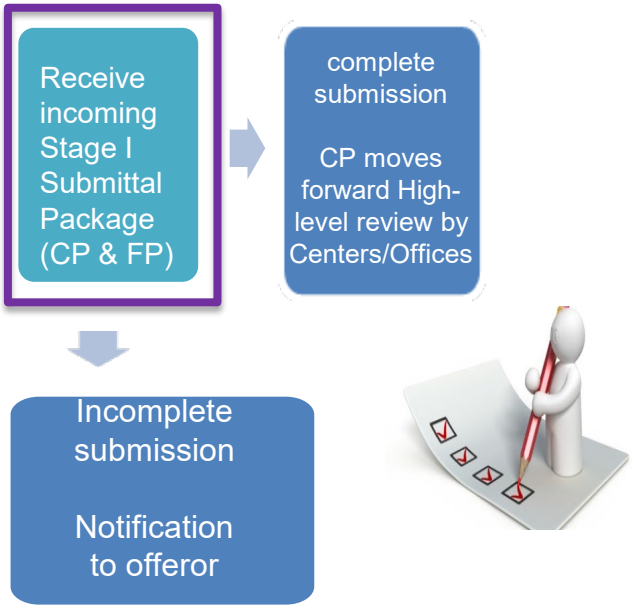
Evaluation Points At Stage I & Stage II



(CP) – Concept Paper ; (FP) - Full Proposal

Evaluation Points At Stage I & Stage II

Preliminary
Review of the proposal
package for completion



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1. Checklist following required template (See attachment 3)
2. Freestanding Concept Paper following required template (See attachment 4)
3. Freestanding Full Proposal following required template (See attachment 5 & Part III)

For further details Part III: Proposal Preparation & Submission
****A submission will be considered incomplete if any critical elements are missing**

(CP) – Concept Paper ; (FP) - Full Proposal

Evaluation Points At Stage I & Stage II

Preliminary
High-level review

Receive incoming Stage I Submittal Package (CP & FP)

CP High-Level Review

Program Relevance established

FP/CP Moves forward to Technical Evaluation Panel Evaluation

Regret Notification

(CP) – Concept Paper ; (FP) - Full Proposal

Evaluation Points At Stage I & Stage II

Stage I

CP/FP will be evaluated by a peer or scientific review process based on the following criteria are in descending order of importance (Sub-criteria listed under a particular criterion are of equal importance):

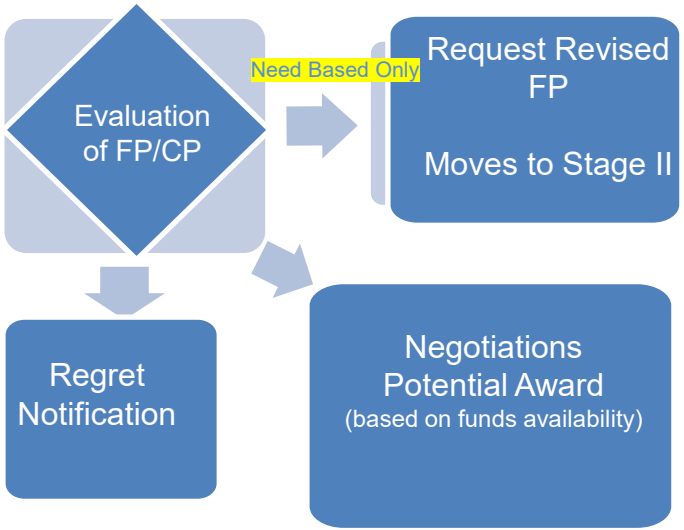
Starting on pg. 76: Part IV: Proposal Evaluation for further details

1. **Scientific and Technical Merit**
2. **Program Relevance**
3. **Capabilities and Experience**

(CP) – Concept Paper ; (FP) - Full Proposal

Evaluation Points At Stage I & Stage II

Stage I
Possible Outcomes

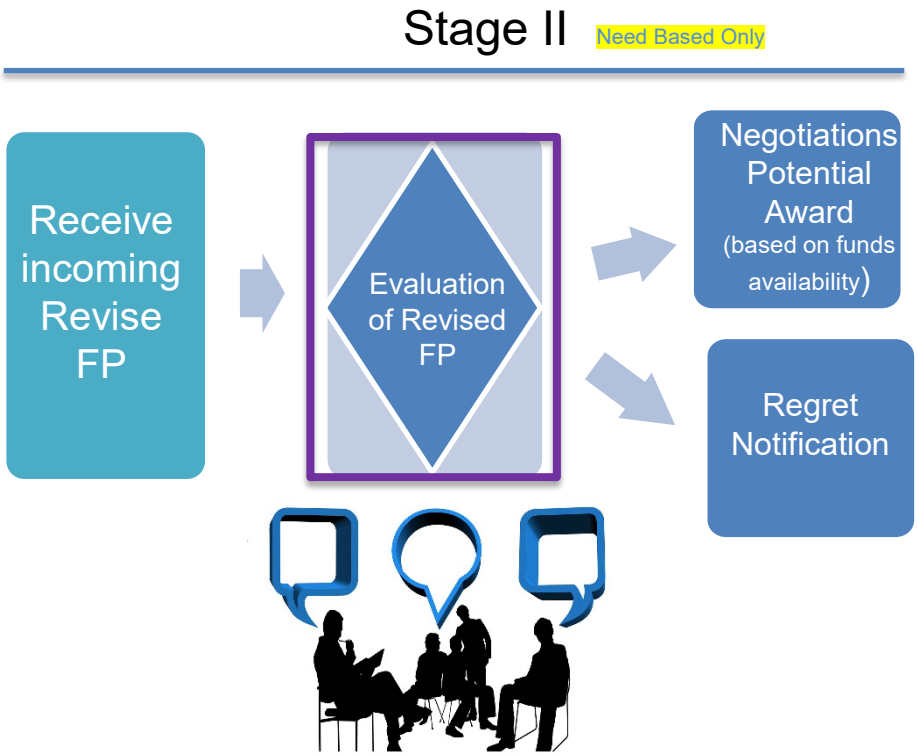


(CP) – Concept Paper ; (FP) - Full Proposal

Evaluation Points At Stage I & Stage II

Revised CP/FP will be evaluated by a peer or scientific review process based on the following criteria are in descending order of importance (Sub-criteria listed under a particular criterion are of equal importance):
Starting on Pg. 76

1. **Scientific and Technical Merit**
2. **Program Relevance**
3. **Capabilities and Experience**



(CP) – Concept Paper ; (FP) - Full Proposal

FY26 Application Process/Dates Reminders

- Submit all required documents for **Stage One Package (Checklist, Concept Paper, Full Proposal), SOW, etc. (See Part III for further details)**

- Submit PDF documents only for required files

- Please contact FDABAA@fda.hhs.gov or BAA contracting Officer (Ian.Weiss@fda.hhs.gov) for any questions or clarifications
  - Please do not contact any other FDA Staff

- Complete all fields of the Concept Paper (Cover Table and Overview; attachment 4) and Full Proposal (See attachment 5 for Volume I- Technical Proposal)

- For FY26 Funding Consideration Stage I submittal Package shall be submitted no later than **5:00 PM Eastern Standard Time* February 24, 2026.**
  Early application are highly encouraged.
  *change from November 21, 2025, solicitation posting

Contact FDABAA@fda.hhs.gov for any additional questions or clarifications