



**ATTACHMENT TO PPM 2023.04-001**

**PREPARED BY:** Acquisition Policy and Oversight Branch

**FROM:** Director, Division of Policy, Systems, and Program Support (DPSPS)

**SUBJECT:** Unsolicited Proposals Attachment “Instructions to Prospective Offerors for Unsolicited Proposals” for FDA Acquisitions to distribute to Prospective Offerors

**EFFECTIVE DATE:** Immediately

**APPLICABILITY:** FDA Acquisitions Personnel and External Potential Offerors

**PURPOSE:**

This document provides instructions to prospective offerors on the preparation and submission of unsolicited proposals to the Food and Drug Administration (FDA). Also, it provides instructions on how the FDA receives, evaluates, and accepts unsolicited proposals.

**GENERAL:**

“Unsolicited proposals allow unique and innovative ideas or approaches that have been developed outside the Government to be made available to Government agencies for use in accomplishment of their missions. Unsolicited proposals are offered with the intent that the Government will enter into a contract with the offeror for research and development or other efforts supporting the Government mission, and often represent a substantial investment and effort by the offeror.”

[See FAR 15.603 - <https://www.acquisition.gov/far/15.603>]

**POLICY:**

Federal policy on the submission of unsolicited proposals states that –

It is the policy of the Government to encourage the submission of new and innovative ideas in response to Broad Agency Announcements, Small Business Innovation Research topics, Small Business Technology Transfer Research topics, Program Research and Development Announcements, or any other Government-initiated solicitation or program. When the new and innovative ideas do not fall under topic areas publicized under those programs or techniques, the ideas may be submitted as unsolicited proposals. [FAR 15.602]

[See FAR 15.602 - <https://www.acquisition.gov/far/15.602>]

**DEFINITIONS:**

An "unsolicited proposal" is –

“a written proposal for a new or innovative idea that is submitted to an agency on the initiative of the offeror for the purpose of obtaining a contract with the Government, and that is not in response to a request for proposals, Broad Agency Announcement, Small Business Innovation Research topic, Small Business Technology Transfer Research topic, Program Research and Development Announcement, or any other Government-initiated solicitation or program.” [FAR 2.101]

A “unique and innovative concept” –

“(1) In the opinion and to the knowledge of the Government evaluator, the meritorious proposal - (i) Is the product of original thinking submitted confidentially by one source; (ii) Contains new, novel, or changed concepts, approaches, or methods; (iii) Was not submitted previously by another; and (iv) Is not otherwise available within the Federal Government. (2) In this context, the term does not mean that the source has the sole capability of performing the research.” [FAR 2.101]

[See FAR 2.101 - <https://www.acquisition.gov/far/part-2>]

**REGULATIONS AND GUIDANCE:**

Unsolicited proposals submitted to FDA are subject to the following acquisition regulations and procedures:

Federal Acquisition Regulation (FAR) Subpart 15.6, Unsolicited Proposals:

<https://www.acquisition.gov/far/subpart-15.6>

Department of Health and Human Services Acquisition Regulation (HHSAR) Subpart 315.605,

Unsolicited Proposals: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-315-contracting-negotiation/index.html#315.6>

**PROCEDURES:**

Preliminary Contacts:

Prospective offerors are encouraged to make preliminary contacts with agency personnel prior to preparing detailed unsolicited proposals or submitting proprietary information to the Government. This may save considerable time and effort for both parties. [See FAR 15.201 and 15.604(a) - (<https://www.acquisition.gov/far/15.201> and <https://www.acquisition.gov/far/15.604>)]

**Information to Prospective Offerors:**

These instructions provide prospective offeror’s information on the preparation and submission of an unsolicited proposal; and an agency’s receipt, evaluation, and acceptance (or rejection) of an

unsolicited offer (<https://www.acquisition.gov/far/subpart-15.6>).

Preliminary contact with agency technical or other appropriate personnel before preparing a detailed unsolicited proposal or submitting proprietary information to the Government may save considerable time and effort for both parties (<https://www.acquisition.gov/far/15.201>).

Agencies must make available to potential offerors of unsolicited proposals at least the following information:

Definition (<https://www.acquisition.gov/far/2.101>) and content (<https://www.acquisition.gov/far/15.605>) of an unsolicited proposal acceptable for formal evaluation.

Requirements concerning responsible prospective contractors (<https://www.acquisition.gov/far/subpart-9.1>), and organizational conflicts of interest (<https://www.acquisition.gov/far/subpart-9.5>).

Guidance on preferred methods for submitting ideas/concepts to the Government, such as any agency: upcoming solicitations; Broad Agency Announcements; Small Business Innovation Research programs; Small Business Technology Transfer Research programs; Program Research and Development Announcements; or grant programs.

Agency points of contact for information regarding advertising, contributions, and other types of transactions like unsolicited proposals. [See <https://www.fda.gov/about-fda/doing-business-fda> for a listing of the FDA's Points of Contact].

Information sources on agency objectives and areas of potential interest. [See <https://www.fda.gov/about-fda/doing-business-fda> and the FedBizOpps Opportunities at <https://sam.gov/content/opportunities>].

Procedures for the submission and evaluation of unsolicited proposals.

Instructions on properly identifying and marking proprietary information and restrictive legends to conform to FAR 15.609. <https://www.acquisition.gov/far/subpart-15.6>.

Note that only the agency's Contracting Officer (CO) has the authority to bind the Government regarding unsolicited proposals. [See FAR 15.604(b).]

**A Valid Unsolicited Proposal Must:**

“(1) Be innovative and unique; (2) Be independently originated and developed by the offeror; (3) Be prepared without Government supervision, endorsement, direction, or direct Government involvement; (4) Include sufficient detail to permit a determination that Government support could be worthwhile and the proposed work could benefit the agency's research and development or other mission responsibilities; and (5) Not be an advance proposal for a known agency requirement that can be acquired by competitive methods.” [See FAR 15.603(c) - <https://www.acquisition.gov/far/15.603>.]

**Content of an Unsolicited Proposal:**

An unsolicited proposal must contain the following to permit consideration in an objective and timely manner [See FAR15.605]:

Basic Information including – (1) offeror's name and address and type of organization; e.g., profit, nonprofit, educational, small business; (2) point of contact information for technical and business personnel for evaluation or negotiation purposes; (3) identification of proprietary data to be used only for evaluation purposes; (4) names of other Federal, State, or local agencies or parties receiving the proposal or funding the proposed effort; (5) date of submission; and (6) signature of a person authorized to represent and contractually obligate the offeror.

Technical information including – (1) concise title and abstract (approximately 200 words) of the proposed effort; (2) reasonably complete discussion stating the objectives of the effort or activity, the method of approach and extent of effort to be employed, the nature and extent of the anticipated results, and the manner in which the work will help to support accomplishment of the agency's mission; (3) names and biographical information on the offeror's key personnel who would be involved, including alternates; and (4) type of support needed from the agency; e.g., facilities, equipment, materials, or personnel resources.

Supporting information including – (1) proposed price or total estimated cost for the effort in sufficient detail for meaningful evaluation; (2) period of time for which the proposal is valid (a 6-month minimum is suggested).

(3) type of contract preferred; (4) proposed duration of effort; (5) brief description of the organization, previous experience, relevant past performance, and facilities to be used; (6) other statements, if applicable, about organizational conflicts of interest, security clearances, and environmental impacts; and (7) names and telephone numbers of agency technical or other personnel already contacted regarding the proposal.

[See FAR 15.605 - <https://www.acquisition.gov/far/15.605>]

Certification by Offeror:

To ensure that an offeror's contacts with agency employees do not exceed the limits of acceptable preliminary contacts and therefore result in an unfair advantage; its unsolicited proposal must include the following:

Certification by Offeror

This is to certify, to the best of my knowledge and belief, that: (a) this proposal has not been prepared under Government supervision. (b) The

methods and approaches stated in the proposal were developed by this offeror. (c) Any contact with employees of the Department of Health and Human Services has been within the limits of appropriate advance guidance set forth in FAR 15.604. (d) No prior commitments were received from departmental employees regarding acceptance of this proposal.

Date:  
Organization:  
Name:  
Title:

(A responsible official of the proposing organization or a person authorized to contractually obligate the organization shall sign this certification.)

[See HHSAR 315.605(d) - <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/part-315-contracting-negotiation/index.html#315.6>]

**Receipt and Initial Review:**

Before initiating a comprehensive evaluation of an unsolicited proposal, the FDA contact point will determine if the proposal (1) meets the requirements of a “valid unsolicited proposal” [See FAR15.603(c)]; (2) is suitable for submission in response to an existing agency requirement [See FAR 15.602]; (3) is related to the agency mission; (4) contains sufficient technical information and cost-related information for evaluation; (5) has been approved by a responsible official or other representative authorized to obligate the offeror contractually; and (6) complies with the marking requirements of FAR 15.609. [See FAR 15.606-1.]

If the unsolicited proposal meets the above requirements, the FDA contact point will promptly acknowledge receipt in writing and process the proposal for evaluation. If FDA rejects an unsolicited proposal because it does not meet the above requirements, the contact point shall promptly inform the offeror of the reasons for rejection in writing and of the proposed disposition of the unsolicited proposal.

**Use and Disclosure of Data Marking Requirements:**

An unsolicited proposal may include data that the offeror does not want disclosed to the public for any purpose or used by the Government except for evaluation purposes. If the offeror wishes to restrict the use of the data, the title page of the unsolicited proposal must be marked with the “Use and Disclosure of Data” legend contained at FAR 15.609(a).

The offeror must also mark each sheet of data it wishes to restrict with the Use and Disclosure of Data legend contained at FAR 15.609(b).

For an unsolicited proposal that contains the Use and Disclosure of Data legends, the FDA contact point will place a cover sheet on the proposal or clearly mark it with the Unsolicited Proposal - Use of Data Limited legend at FAR 15.609(d), unless the offeror clearly states in writing that no restrictions are imposed on the disclosure or use of the data contained in the proposal.

**Evaluation of an Unsolicited Proposal. FDA uses the following factors to evaluate an unsolicited proposal:** [See FAR 15.606-2]

Unique, innovative, and meritorious methods, approaches, or concepts demonstrated by the proposal;

Overall scientific, technical, or socioeconomic merits of the proposal;

Potential contribution of the proposed effort to the agency's specific mission;

The offeror's capabilities, related experience, facilities, techniques, or unique combinations of these which are integral factors for achieving the proposal objectives;

The qualifications, capabilities, and experience of the proposed principal investigator, team leader, or key personnel critical in achieving the proposal objectives; and

The realism of the proposed cost.

FDA procedures require three or more experts, the majority of whom are not required to make recommendations concerning the acquisition as part of their official duties, evaluate the unsolicited proposal. Unsolicited proposals that meet the definition of research and development require peer review.

**Acceptance and Negotiation of an Unsolicited Proposal:**

A favorable comprehensive evaluation of an unsolicited proposal does not, in itself, justify awarding a contract without providing for full and open competition. An unsolicited proposal shall be returned to an offeror, citing reasons, when its substance: (1) is available to the Government without restriction from another source; (2) closely resembles a pending competitive acquisition requirement; (3) does not relate to the FDA activity's mission; or (4) does not demonstrate an innovative and unique method, approach, or concept, or is otherwise not deemed a meritorious proposal. [See FAR 15.607(a).]

The CO may commence negotiations on a sole source basis only when: (1) an unsolicited proposal has received a favorable comprehensive evaluation; (2) a justification and approval has been obtained; and (3) the agency technical office sponsoring the contract furnishes the necessary funds. [See FAR 15.607(b).]

[See FAR 15.06 - <https://www.acquisition.gov/far/subpart-15.6>]

**Synopsis Requirements:**

The CO need not issue a public synopsis of the proposed contract action if it results from the acceptance of an unsolicited research proposal that demonstrates a unique and innovative concept and publication of any notice would improperly disclose the originality of thought or innovativeness of the proposed research or would disclose proprietary information associated with the proposal. [See FAR 5.202(a)(8) - [https://www.acquisition.gov/far/part-5#FAR\\_5\\_202](https://www.acquisition.gov/far/part-5#FAR_5_202)]

This exception does not apply if the proposed contract action results from an unsolicited research proposal and acceptance is based solely upon the unique capability of the source to perform the research services proposed. [See FAR 6.302-1(a)(2)(i) - <https://www.acquisition.gov/far/6.302-1>]

5/4/2023

**X** Bryan E Jones

---

Bryan E. Jones  
Director, Div. Policy, Systems and Pgm. Support  
Signed by: PIV

