

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

PROCUREMENT AND SUPPLY MANAGEMENT

PROCUREMENT

UNSOLICITED PROPOSALS

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1. PURPOSE

This guide prescribes Food and Drug Administration (FDA) policy and procedures for reviewing and processing unsolicited proposals received by the FDA. It implements Federal Acquisitions Regulations subpart 15.5, and HHS Acquisition regulation, subpart 315.5, "Unsolicited Proposals."

2. DEFINITIONS

A. Unsolicited Proposal. A written proposal to perform research and development, including studies, surveys, and demonstrations in socioeconomic areas submitted to the Government by an organization or individual solely on its own initiative and **without prior formal or informal solicitation**. It does not pertain to the procurement of supplies or other types of services. Unsolicited proposals purport to represent original effort by the offeror in the form of new and unique ideas, and are offered in the hope that the Government will support the offer in the further pursuit of the activities proposed therein.

B. Coordinating Officer. FDA's point of contact established to coordinate the administrative control and processing of unsolicited proposals, hereafter called coordinating officer.

C. Center or Office Unsolicited Proposal Contact Point. A point of contact established within each center or office to interface with the Agency's coordinating officer in processing an unsolicited proposal, hereafter called office or center unsolicited proposal contact point.

D. Preliminary Review. A non-scientific review to determine if an unsolicited proposal is truly unsolicited and meets the criteria set forth herein.

E. Comprehensive Evaluation. A review by program personnel, or by a peer review group to determine the overall scientific and technical merit of the proposed effort, and to determine if the proposal supports the mission of the center or office concerned.

3. POLICY

It is the policy of FDA to make prompt acknowledgment of all unsolicited proposals, followed by reasonable expeditious processing, committee review as warranted, and final disposition and notification of action taken.

4. PROCEDURE

A. General.

1. All unsolicited proposals received in FDA by an individual or organization shall be promptly forwarded upon receipt, to the coordinating officer for administrative control and other appropriate action.
2. Immediately upon receipt, the coordinating officer shall send a letter to the offeror acknowledging receipt of the proposal. After preliminary review, the coordinating officer shall provide a copy of the preliminary review and the unsolicited proposal to the office or center contact point for coordination with the center or office program staff for a comprehensive evaluation.

B. Designated Coordinating Officer.

The Principal Official Responsible for Acquisition has designated the Chief, Policy and Evaluation Branch, DCGM, (HFA-505), as FDA's unsolicited proposal coordinating officer.

C. Designation of Office or Center Contact Points.

1. Each office or center shall appoint a person within their organization to be the **unsolicited proposal contact point**. The Associate Commissioner for Management shall appoint one person as the single unsolicited proposal contact point. The Associate Commissioner for Management shall appoint one person as the single unsolicited proposal contact point for all of the eight offices of the Commissioner.

2. The office or center shall provide to the Chief, Policy and Evaluation Branch, DCGM, the name, location and telephone number of the person appointed.

5. REVIEW PROCEDURE

A. Preliminary Review.

1. The unsolicited proposal coordinating officer, with the assistance of a contracting officer and/or program personnel, shall perform a preliminary review of the unsolicited proposal to determine that it:
 - a. Contains sufficient technical and cost information to enable meaningful evaluation;
 - b. Has been approved by a responsible official of the proposing organization or a person authorized to contractually obligate such organizations; and
 - c. Complies with the marking requirements cited in FAR 15.5 and HHSAR 315.5.
 - d. Does not merely offer to perform standard services, such as routine analyses or testing in accordance with established procedures, or to provide "off-the-shelf" articles.
2. In addition, the coordinating officer shall, after conferring with office or center program personnel, **make a written determination as to whether the document is truly unsolicited.** In making such determinations, consideration shall be given to all relevant circumstances, including whether the document may have resulted from:
 - a. The close professional relationships that frequently develop between Agency representatives and their counterparts in the private sector; or
 - b. The inadvertent disclosure by program personnel of information relating to specific projects being contemplated.
3. If the document does not meet the requirements of paragraph 5.a.(1) and 5.a.(2), a comprehensive evaluation need not be made, and the document may be considered and handled as correspondence or advertising. In such cases, a letter shall be sent to the offeror, by the coordinating officer, indicating how the document is being interpreted and the reason(s) for not considering it an unsolicited proposal.

4. When a document, based upon the preliminary review, qualifies as an unsolicited proposal, it shall be circulated for comprehensive evaluation in accordance with paragraph 5.b., below. The coordinating officer shall send a copy of the unsolicited proposal, together with the written preliminary review, as described in paragraph 5.a.(1) and 5.a.(2), to the appropriate office or center contact point.

B. Comprehensive Evaluation.

1. The appropriate office or center unsolicited proposal contact point shall insure that a comprehensive evaluation of each unsolicited proposal is conducted according to approved Agency procedures to determine:
 - a. The overall scientific and technical merit of the proposed effort;
 - b. The unique capabilities, related experience, facilities, instrumentation, or techniques which the offeror possesses and offers, and which are considered to be integral factors for achieving the scientific, technical, and/or technological objective(s) of the proposal;
 - c. The unique qualifications, capabilities, and experience of the proposed principal investigator and/or key personnel;
 - d. The relevance, priority and/or need of the proposal as it relates to the overall program objectives, and the agency's specific mission;
 - e. The availability of funding and identification of the sponsor who will have the responsibility for initiating an appropriate Memorandum of Need.
2. The written evaluation setting forth the information above shall be forwarded to the Agency's Coordinating Officer.
3. If an unsolicited proposal is not to be accepted based on the criteria set forth in paragraph 5.b.(1), the office or center contact person shall notify the coordinating officer of the decision, setting forth the reason(s) and basis for the decision. The offeror shall be notified, in writing by the coordinating officer, of the Agency's rejection of the unsolicited proposal.

6. PROCUREMENT PROCEDURE

- A. When an unsolicited proposal has received a favorable review as set forth in paragraph 5., procurement can proceed only after a Justification for

Other than Full and Open Competition (JOFOC) for the unsolicited proposal has been written by the respective center and accepted by the Division of Contracts and Grants Management (HFA-500). The JOFOC shall be written by the program personnel of the sponsoring office or center, with assistance from the coordinating officer. The format and approval levels for the justification shall be in accordance with the instructions for JOFOCs set forth in SMG 2610.11. When the JOFOC is accepted, the proposed work delineated in the unsolicited proposal may be procured from the offeror on a noncompetitive basis. If the proposed procurement does not meet all of the criteria for a sole source procurement, the requirement will be solicited on a competitive basis.

- B. The appropriate center or office shall initiate procurement action of the approved unsolicited proposal by processing a Memorandum of Need, in accordance with Staff Manual Guide FDA 2610.1, with the unsolicited proposal and comprehensive evaluation attached.
- C. Centers and offices are reminded that no commitment should be made to the offeror by program personnel, since only the contracting officer has the authority to commit the Government to any contractual action.
- D. The Division of Contracts and Grants Management, upon receipt of the fully approved Memorandum of Need, shall initiate procurement action in accordance with prescribed procurement procedures.