Sources Sought Notice:

Sources Sought Notice No: HHS-NIH-NCI-SS-PCPSB-15004-70

Title: "Regulatory Support for Cancer Prevention Agent Development"

The Division of Cancer Prevention (DCP) of the National Cancer Institute (NCI) is planning to award a contract for the regulatory support of cancer prevention agent development. This Small Business Sources Sought notice (SBSS) is for informational and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute (NCI).

The purpose of this SBSS notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. **An organization that is NOT considered a small business under the applicable NAICS code should NOT submit a response to this notice.**

The NAICS code for the project is 541690.

The small business size standard is $7 Million.

Background:

The Division of Cancer Prevention has over 40 active clinical trials, 15 trials in development and is the sponsor for approximately 35 INDs (Investigational New Drug Applications). DCPs INDs are located in six Divisions at the Food and Drug Administration (FDA). The mission of DCP is to plan and direct cancer prevention research, including testing promising agents in human clinical trials as part of a drug development program. Such testing falls under the purview of regulatory agencies such as the FDA and requires certain documentation for the use of the investigational agent. The collection, preparation, submission and continual update of this documentation is the focus of this acquisition.

Purpose and Objectives:

The purpose of the acquisition is to continue a well-established regulatory affairs program providing services to support the preparation, processing, management and storage of regulatory affairs documentation.

Project Requirements:

The proposed acquisition will involve the following type of activities:

1) Provide regulatory submissions to support the DCP's chemoprevention agent development and clinical research program,
2) Prepare, review, maintain, and track correspondence related to regulatory submission,
3) Provide regulatory support for safety data (adverse event) review, processing, and submission to regulatory agencies and investigators

4) Maintain electronic and paper files of agreement documents and other documents from pharmaceutical companies,
5) Assist in scheduling, facilitating, and attending meetings to support DCP's regulatory affairs, agent development, and clinical research programs,
6) Manage regulatory documents such as Investigational New Drug Applications (INDs) and Drug Master Files (DMFs) in paper and electronic format in accordance with regulations, laws, and guidance,
7) Perform regulatory and safety reviews, reporting and advisory activities,
8) Prepare, process and establish a written plan for quality assurance and quality control of all data and procedures,
9) Maintain and enhance standard procedures for information management to support DCP's regulatory affairs, and
10) Assist in the transition of the existing contract to the successor contractor.

Capability Statement/Information Sought:

Small businesses that believe that they have the ability to satisfy all of the above stated Project Requirements, and who meet the stated size standards, are encouraged to submit a capability statement. On the first page of the capability statement, clearly state the small business concern's size status and type(s), name, address, point of contact, and DUNS number.

To be deemed capable, the offeror must submit a written capability statement based on the Project Requirements and the current in-house capacity to perform the work and must demonstrate that similar work has been performed in the past. Organizations that submit capability statements in response to this notice will be evaluated against the following technical areas of experience and expertise:

1. **Technical approach**
    a. Demonstration of an understanding of the needs of the project and regulatory affairs.
    b. Standard Operating Procedures in place for the task areas.

2. **Personnel**
    a. The offeror shall document staff experience to conduct this work. It should be clear to the reviewers how the respective education, training, and expertise of the offeror's proposed staff relates to the needs of the project.

3. **Facilities**
    a. Proof of adequate facility space.

4. **Organizational Experience**
    a. History of key personnel having prior experience as a team in core competencies.

Anticipated Period of Performance:

The anticipated period of performance is for five years with two option years, starting about September 2011.

Information Submission Instructions:

The capability statement should be limited to no more than twenty (20) single-sided pages (including all attachments, resumes, charts, etc.), presented in single-spaced using a 12 point

font size at a minimum. All proprietary information should be marked as such. The capability statement should include an indication of current certified small business status; this indication should be clearly marked on the first page of the statement (preferably placed under the eligible small business concern's name and address). Responses will be reviewd only by NIH personnel and will be held in a confidential manner. If responses indicate the likelihood of satisfactory competition among qualified businesses, the anticipated solicitation will be restricted to small businesses only.

All capability statements sent in response to this SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via email) to Erin C. Lange, Contracting Officer, at langee@mail.nih.gov in either MS Word, WordPerfect, or ADOBE Portable Document Format (PDF), by **March 18, 2011, 2:00PM EST**. Questions regarding this requirement must be submitted in writing and directed to Erin C. Lange at the above email address before the closing date of this notice. **All responses must be received by the specified due date and time in order to be considered.**

Disclaimer and Important Notes:

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use the 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 Government to determine the organization's qualifications to perform the work. Respondents are advised that the 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 determination will be made as to whether the project will or will not be set-aside for small businesses. At a later date, a pre-solicitation synopsis and solicitation [Request for Proposal (RFP)] may be published in Federal Business Opportunities (http://fbo.gov). **However, responses to this notice will not be considered adequate responses to a solicitation.**

Confidentiality:

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation.

Primary Point of Contact:

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