SMALL BUSINESS SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-27024-82
Title: Analysis of Anti-Cancer Chemicals & Pharmaceutical Formulations

This is a Small Business Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this 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.

This National Cancer Institute (NCI), National Institutes of Health (NIH) project is a recompetition of an existing requirement. This Small Business Sources Sought Notice (SBSS) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute. A determination by the Government not to compete this requirement as a set-aside based upon responses to this Notice is solely within the discretion of the Government. Interested parties are expected to review this Notice and the draft **Statement of Work** to familiarize themselves with the requirements of this project; failure to do so will be at your firm's own risk.

Background:
The analytical contract services constitute a program resource responsible for evaluating the identity and purity of active pharmaceutical ingredients and formulated drug products. Completed analytical reports on bulk drug substances and dosage forms provide the basis for assessing their suitability for use in advanced anti-tumor screening, toxicological studies, formulation studies and for clinical trials. These data are also submitted to the Food and Drug Administration (FDA) as a required portion of the NCI's Investigational New Drug (IND) filings for investigational anti-tumor agents. Historical summaries of the analytical data are used in preparing specifications of various active pharmaceutical ingredients, for procurement actions and routine quality control of these materials. The methods and data are also provided to other contract projects for implementing shelf-life monitoring, facilitating formulation development, and supporting the analytical aspects of pharmacological and toxicological testing.

Purpose and Objectives:
The purpose of this Small Business Sources Sought Notice is to identify qualified small business concerns including 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 that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information submitted.

As a result of this SBSS Notice, the NCI may issue a Request for Proposal (RFP). **THERE IS NO SOLICITATION AVAILABLE AT THIS TIME.** However, should such a requirement materialize, no basis for claims against NCI shall arise as a result of a response to this Small Business Sources Sought Notice or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

The purpose of this project is to provide services for the analysis of bulk drug substances and formulated drug products. Various objectives to be achieved under this project as defined under Section B of the attached draft Statement of Work may include the following:

1. Establish the identity of the drug substance, usually by a combination of spectroscopic and spectrometric studies.
2. Establish the purity of bulk drug substance, usually by the development of a validated chromatographic method according to FDA guidance.
3. Identify and determine the amounts of major impurities present in the bulk drug substance, primarily by a combination of chromatographic and spectroscopic/spectrometric analyses and preferably by LC-MS (liquid chromatography-mass spectrometric analysis).
4. Determine the physical and chemical properties of drug substances (e.g., solubility, optical rotation, thermal properties (m.p., DSC, TGA), partition coefficient and pKa's).
5. Determine the stability of the drug substance and drug product under designated storage conditions, in accordance with FDA guidance.
6. Identify and determine the concentration of the active pharmaceutical ingredient in dosage forms.
7. Determine weight variation and content uniformity of dosage forms.
8. Develop dissolution method for solid dosage forms.
9. Adapt bulk drug substance assay methods to allow the determination of drug levels in plasma or other complex matrices.

Project Requirements:
In order to meet the objectives listed above, the Contractor shall be expected to analyze bulk drug substance and formulated drug product. The Contractor shall also develop validated analytical methods to establish the identity and purity of the materials analyzed. The draft Statement of Work should be referenced for further information.

Anticipated Period of Performance:
The period of performance for this requirement will be a one-year base period with four (4) successive one-year options, for a total of five years if all options are exercised. The anticipated start date is June 1, 2012.

Other Important Considerations:
Draft Statement of Work:
A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Office of Acquisitions Website at URL: http://rcb.nci.nih.gov/ . Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:
In the event an RFP is issued, North American Industry Classification System (NAICS) code 325412 with a size standard of 750 employees is being considered.

Capability Statement/Information Sought:
Tailored Capability Statements shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW). Tailored Capability Statements for this requirement shall address the following six (6) areas (mandatory qualifications, information on similar projects, technical approach, personnel, facilities/equipment and corporate experience):

1. Please indicate whether or not the proposed facility meets FDA standards for Laboratory Quality Unit in accordance with current Good Manufacturing Practice (cGMP) regulation, including compliance with all Occupational Safety and Health Act (OSHA) and United States Department of Transportation (DOT) regulations regarding the handling of chemicals. In addition, address compliance with all United States Environmental Protection Agency (EPA) regulations regarding discharge of water and air pollutants and assure that disposal of all chemical residues meet current EPA regulations. If your organization currently does not meet these requirements, please be advised that they must be met at the time of receipt of initial proposals by the Contracting Officer in order for the proposal to be considered for award.

2. Document experience with contracts of a similar size and scope to this proposed project. Contract(s)/project(s) listed may include those entered into by the Federal Government, agencies of state or local governments, and commercial concerns. The following information shall be submitted to document this experience: Name of contracting organization; Contract number (for subcontracts, provide the prime contract number and the subcontract number); Contract type; Total contract value; Description of the requirement; Contracting Officer's name and telephone number; and Standard Industrial Code or NAICS code.

3. A detailed Technical Approach that demonstrates a clear understanding of the draft SOW. Specifically your Capability Statement shall, (a) describe your awareness and understanding of problems associated with the analysis of bulk drug substances and clinical dosage forms; (b) discuss proposed approaches to the resolution of such problems; (c) discuss approaches to analytical method development of drug substance; describing two (2) representative examples for drug substances that are technically challenging; (d) discuss approaches to the definitive structural elucidation of a drug substance; describing two (2)

representative examples for drug substances of high structural complexity; and (e) indicate the systems/procedures to be used to ensure that the various activities will be scheduled according to their priority.

4. The proposed Personnel shall demonstrate that your organization has the necessary expertise to perform the requirements of the project. Capability Statements must demonstrate that the personnel experience stated in the Capability Statement occurred in conjunction with projects comparable in size and complexity. The proposed Principal Investigator (PI) must be thoroughly familiar with the analysis of bulk pharmaceutical substances and clinical dosage forms. It is recommended that the PI commit not less than 50% of his/her time to this project. The PI must be trained in Chemistry (Analytical, Pharmaceutical, Organic, etc.), preferably at the Ph.D. level from an accredited school. The PI must have at least three (3) years of recent experience in the analysis of drug substances and drug products. If not trained at the Ph.D. level, the PI must have at least a Master's Degree with a minimum of five (5) years of recent experience in the analysis of drug substances. He/she should also have three (3) years of recent experience in the analysis of clinical dosage forms.

   A Principal Assistant (PA) should also be assigned to this project. The PA should be an individual of extensive, relevant analytical experience capable of independently supervising and coordinating the actual laboratory work. Describe background training, recent experience and accomplishments that qualify the individual to lead this project. Include the Principal Assistant's updated curriculum vitae with a listing of scientific publications. Indicate the individual's availability and proposed level of effort.

   A clear, specific plan must be presented whereby either the Principal Investigator or the Principal Assistant will be on the job managing the project every day of the contract and available for consultation with the Government Contracting Officer's Representative. Although neither the PI nor the PA are required to be committed full-time to this project, it is essential that one of them be on the job every working day.

   Describe the background, training, recent experience and accomplishments of additional personnel that qualify each individual to perform in their area of responsibility.

   For information purposes, it is estimated that 6,563 direct labor hours of effort will be required on a yearly basis.

5. The Capability Statement shall provide evidence of having all necessary equipment and instrumentation for all aspects of the analytical assessment of bulk drug substances and formulated drug products. The facility shall be equipped with refrigeration and deep freeze storage for the analytical samples and reference materials and shall have a dry box and fume hoods for the proper

handling of materials. The Government will not be providing equipment for use on this project; therefore, the contractor shall provide evidence that the equipment and instrumentation identified in this draft SOW shall be accessible and available for immediate use on this project.

6. The Related Experience of the Company must clearly address the capability of the organization to meet the above requirements. Documentation of this experience must include examples of relevant recent experience providing analysis of bulk drug substances and formulated drug products with Government or non-Government agencies. Clearly describe related work within the past two (2) years (of offeror and subcontractors, if any) showing contract number, name of respective contractor's program manager, client name, brief description of work, start and completion dates and approximate funding and contract value, and names and phone numbers of individuals who may be contacted as references for work that is cited. NCI may contract these references and to use that information in the evaluation of the Capability Statement. Document company/organizational experience in the following must also be addressed: (a) experience providing the full range of services outlined in the draft SOW for projects of the same/similar size and magnitude as outlined in the draft SOW; (b) providing services related to the analysis of bulk drug substances and clinical dosage forms of the same/similar size and magnitude as outlined in the draft SOW; and (c) capability of managing projects efficiently and resolving problems quickly.

Information Submission Instructions:

1. Page Limitations:
Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty-five (25) single-sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address), as well as the eligible small business concern's name, point of contact, address and DUNS number.

2. Number of Copies/Delivery Point:
All capability Statement sent in response to this SMALL BUSINESS SOURCES SOUGHT notice must be submitted electronically (via e-mail) to Amy Stull, Contract Specialist, at stullac@mail.nih.gov and C. Timothy Crilley, Contracting Officer, at tcrilley@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF). The e-mail subject line must specify HHS-NIH-NCI-SBSS-TSB-27024-82. Facsimile responses will not be accepted.

3. **Common Cut-off Date:**
Electronically submitted tailored capability statements are due no later than 2:00 PM (Eastern Prevailing Time) on December 8, 2011. ***CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT 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 this response. The Government reserves the right to use 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 is received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. 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 nonproprietary technical information in any resultant solicitation(s).