

Attachment #8:

Sources Sought Notice

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 there are small businesses; HUBZone small businesses; service-disabled sources; veteran-owned small businesses; 8(a) small businesses; veteran owned small businesses; woman-owned small businesses; or small disadvantaged business; and (3) their size classification relative to 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.**

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.

Interest parties are expected to review this notice and the draft Statement of Work to familiarize themselves with the requirement of this project; failure to do so will be at your firm's own risk.

Background:

The Drug Synthesis and Chemistry Branch (DSCB) of the Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) has the responsibility for the acquisition of organic and inorganic chemical compounds as potential antitumor agents. The Government is seeking a Contractor with established expertise in the field of synthesis of organic and inorganic compounds to prepare those deemed of interest to the program for evaluation of antitumor agents.

This project will support the program objectives of DSCB by accomplishing the following specific objectives:

- A. Synthesize samples of compounds which have been designated of interest to the DTP drug discovery and development program that are not available from the original sources. Compounds may be required for either primary screening or follow-up testing of pharmacology studies.
 1. The overall objective of the contract will be the "non-GMP" chemical synthesis of compounds of good purity, as deemed acceptable by the Contracting Officer's Technical Representative (COTR), needed for the cancer program, such as synthetic compounds prompted by the NCI Experimental Therapeutics (NExT) Program and compounds arising from

recommendation of the Biological Evaluation Committee (BEC). The existing contract will not be utilized for the synthesis of combinatorial libraries. The new acquisition contract that will emerge from this RFP will be utilized for the purpose of synthesizing lead compounds and their analogs. At times, the need may arise to prepare analogs via parallel synthesis to achieve the goals of the CBC initiative.

2. Compounds assigned for synthesis will be primarily antitumor agents and include, but not be limited to, carbocycles, heterocycles typically containing nitrogen, oxygen, and sulfur, carbohydrates, nucleosides and metal coordination complexes.
 3. Amounts of compounds to be synthesized will vary widely but will usually be in the range from 200 mg to 100 grams.
- B. Synthesize, by conventional or parallel synthesis techniques, small series of compounds closely related, structurally, to active leads identified by DSCB.
- C. Determine selected physical and/or chemical data on compounds (i.e., purity solubility, stability, etc.) which will aid in determining testing, formulation and storage conditions.

Check purities of compounds supplied by the NCI as needed.

Additional Background Information

DESCRIPTION of the PROJECT/SUPPLIES/SERVICES.

The mission of the Developmental Therapeutics Program (DTP) is the identification of novel synthetic and natural products as potential anti-cancer agents. Toward this mission, the contract will be devoted to the synthesis of small molecules needed by the various programs of the Division of Cancer Treatment and Diagnosis (DCTD).

This contract will provide synthesis support for the early stages of the drug discovery and development program. The compounds assigned for the synthesis originate from the DCTD's NExT program and the Biological Evaluation Committee (BEC) recommendations. The synthesis work involved in this contract originates from the above mentioned programs. Synthesis of analogs in order to improve the potencies and pharmacodynamic properties of lead compounds where the core chemistry is either well established or unknown also would fall

within the scope of the contract. In addition, the contract will be utilized to check the purity and identity of selected compounds as needed. The purity and identity of all resynthesized compounds and intermediates will be established by state-of-the-art analytical chemistry methods. The quantities synthesized would generally vary from 200 mg to 100 grams.

Under this contract the successful offeror may be required to synthesize small (combinatorial) libraries by parallel synthesis. Outlines of synthetic routes, and more commonly, detailed experimental procedures obtained from the literature, will be available for the majority of the assignments. Development of synthetic methods may be required in those cases where no procedures are available, or when the published methods prove unreliable in practice.

Assignments of compounds to be synthesized as well as project priorities will be determined by the COTR. Compounds to be synthesized will embrace a wide variety of structural classes (e.g., carbocyclics, heterocyclics, natural products), which would involve diverse capability in organic and inorganic synthesis.

The NCI signs legally binding agreements with some suppliers (often pharmaceutical or chemical companies) which state that all information on compounds donated by those suppliers will be held confidential. The occasion may arise whereby the successful offeror will be assigned to synthesize such a confidential compound or modify the target. If the Contractor were a chemical or pharmaceutical company they could gain valuable data on confidential new lead compounds. The NCI believes that in order to honor the confidentiality agreement with suppliers, and in order to avoid any chance of transmitting privileged data to a competitor, pharmaceutical and chemical companies must be excluded from the competition.

A pharmaceutical or chemical company is defined as an organization which sells drugs and/or chemicals to the general public for profit. A subsidiary of a Pharmaceutical or chemical company, which prepares bulk drug substance for the parent company is also excluded from the competition.

The Contractor will have access to proprietary information on compounds assigned by the NCI for re-synthesis and the Contractor shall be required to treat all information obtained under this contract as strictly confidential. The Government will provide the Contractor with guidelines governing this requirement.

The proposed contract will consist of a five (5) year (multi-year), cost-plus-fixed-fee contract. Synthesis and deliveries of an average 15 to 25 target compounds, excluding synthetic intermediates would be expected each year with a total of 75 to 125 required over the five (5) year contract period.

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; women-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 received.

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 claim against the 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 specification for any subsequent requirement.

If a RFP is issued, the NCI anticipates multiple awards may result from the issuance of the RFP.

Project Requirements:

- Assigned compounds are not readily available in the quality or quantity required from the original source, other suppliers or the open market. The compound could be known or new chemicals with a wide variety of chemical structures.
- Multi-step preparation sequences will generally be involved and process development for scale-up preparation will be expected using provided investigator's procedures.
- The quantity of a given material synthesized may range from multi-grams to multi-kilograms.
- All materials prepared will be fully characterized for high purity and the preparation cost will also be calculated.
- Most of the assigned projects should be performed under good manufacturing practices (cGMP) complied with the Food and Drug Administration (FDA) rules and regulations.
- If an award is made, the resultant Contractor will have access to proprietary information on compounds assigned by the NCI for synthesis. The Contractor shall be required to treat all information obtained under the resultant contract as strictly confidential. Any disclosure of any portion of such compounds shall require written authorization from the Government.

Anticipated Period of Performance:

The period of performance for this requirement is five (5) years, consisting of a one year base period, and four one-year options. The anticipated state date is on or about March 31, 2012.

Other Important Considerations:

A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Officer of Acquisitions Website at <http://rcb.nci.nih.gov/> (in event you are unable to access the SOW attachment provided with this announcement). Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:

In event an RFP is issued, the NAICS code is 54171 and a size standard of 500 employees.

Capability Statement/Information Sought:

Sources are expected to have the personnel, facilities, equipment, and experience to outline a strategy and propose the specifications for the purchase or synthesis of compounds not readily available in the quality or quantity required.

Tailored capability statements shall demonstrate a clear understanding of all tasks specified in the draft SOW, to include document understanding of the multi-step preparation sequences as outlined in the draft SOW. Tailored Capability Statements for this requirement shall also address the following areas:

1. Documented understanding of laboratory workflows;
2. Approach and documented history of multi-step preparation sequences;
3. Demonstrated knowledge of and ability to handle cytotoxic agents;
4. Ability to deliver 8 to 12 synthesis per year;
5. Documented track record of senior personnel with experience to implement an effective synthesis;
6. Any agreements and/or arrangements with subcontractors – explain how the SOW will be accomplished within this working arrangement;
7. Documented current facilities and equipment, capability and past experience in managing potentially hazardous and/or toxic materials;
8. Unique arrangements, equipment or etc. which few organizations are likely to have, which may be advantageous for effective implementation of this project;
9. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project;

10. Documented experience in the development and management of a project of this magnitude.
11. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work are not acceptable. Offerors must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objective.

Information Submission Instructions:

1. **Page Limitations:** Interest qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty-four (24) 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. **Deliver Point:**

All capability statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to Brenda Oberholzer, Contract Specialist, at oberholzerb@mail.nih.gov with a cc to MaryAnne Golling, Contracting Officer, at gollingm@mail.nih.gov in MS Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-SBSS-TSB-17028-11. Facsimile responses will not be accepted.

3. **Common Cut-Off Date:**

Electronically submitted tailored capability statements are due no later than 2:00 PM (Easter Prevailing Time) on Thursday, July 28, 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 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

organizations 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 pre-solicitation notice 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 non-proprietary technical information in any resultant solicitation(s).