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 Pharmaceutical Resources Branch (PRB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment, and Diagnosis (DCTD), National Cancer Institute (NCI), is seeking a contractor to evaluate shelf life of samples of investigational clinical drug formulations. The products may include parenteral, oral, and other types of dosage forms. The results of such testing and evaluations will be provided promptly to the PRB.

Currently there are approximately 20 lots of NCI drug products on stability testing, including both injectable and oral products. These will require approximately 20-25 separate evaluations per year. It is anticipated that there will be approximately 10 new clinical lots each year requiring shelf life determination. The contractor shall store, and properly evaluate quality of each one of these products, insuring that no scheduled time points are missed or overlooked.

The analytical instrumentation shall include sufficient capability to perform high performance liquid chromatography, ultraviolet and infrared spectroscopy, gas liquid chromatography, moisture determinations, pH determination, and particle size determination.

The following MANDATORY QUALIFICATION CRITERIA must be met at the time of receipt of final proposals by the Contacting Officer in order to be considered:

The organization shall have demonstrated GMP experience in the shelf life evaluation of human drug products.

Shelf-life is a FDA regulated requirement.

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:

Evaluate shelf life of samples of investigational clinical drug formulations. The products may include parenteral, oral, and other types of dosage forms. The results of such testing and evaluations will be provided promptly to the PRB. These reports will be used for:

- providing NCI and its investigators with information regarding the proper storage and handling of various drug products under investigation,
- determine continued conformance to the assigned specifications, and
- to support NCI's Investigational New Drug Applications (INDs) filed with the Food and Drug Administration (FDA).

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 February 1, 2013.

NAICS Code and Size Standard:
In event an RFP is issued, the NAICS code is 325412 and a size standard is 750 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. Demonstrated knowledge of and ability to handle cytotoxic agents;

3. Documented track record of senior personnel with experience to implement an effective evaluation plan.

4. Documented current facilities and equipment, capability and past experience in managing potentially hazardous and/or toxic materials;

5. Documented experience in the development and management of a project of this magnitude.

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 Heidi Crawley, Contracting Officer, at crawleyha@mail.nih.gov in MS

Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-SBSS-TSB-37002-05. Facsimile responses will not be accepted.

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

   Electronically submitted tailor capability statements are due no later than 2:00 PM (Easter Prevailing Time) on Tuesday, June 22, 2012. 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).