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 contractors for formulation development services. Formulation for intravenous, oral and other routes of administration will be required for all clinically evaluated compounds. Some compounds exhibit adequate pharmaceutical properties per se. However, some compounds present significant solubility, stability, and or bioavailability problems that are not amenable to solvent approaches or pH adjustment, but may require long range studies depending on Program needs and/or judgment of the P.O.

The National Cancer Institute is seeking contractors to 1) develop acceptable dosage forms for compounds to be subsequently evaluated in cancer patients and 2) to carry out innovative approaches and studies leading to more effective delivery of compounds possessing limited solubility, stability and/or bioavailability. The workload, for each contract, will likely be two to three (2-3) compounds for full-scale, and several small projects per year. NCI will select and provide the compounds to be studied. When available, analytical chemistry data will also be sent by the NCI.

In addition to solubility studies, the projects may require analytical work, particularly the development of a stability-indicating assay to monitor the integrity of the parent compound during the formulation development and in the final formulated product. Also, depending on the desired dosage form, the P.O. will guide the contractor to conduct necessary pre-formulation studies on the compounds of interest. These investigations will be directed toward a pharmaceutical dosage form that will meet certain solubility and adequate stability acceptable by the Government. The Contractor will provide a pilot batch of finished dosage forms and a written final project report. The contractor may also be asked to conduct bioavailability enhancement studies; therefore, capability to conduct bioavailability studies in

experimental animal is also required. The National Cancer Institute at its discretion will perform toxicity testing in laboratory animals of new dosage forms and/or delivery systems, new excipients and/or vehicles and confirmation of biologic activity of experimental formulations.

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:

The Contractor shall furnish services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work described below:

1. Determine the solubility profile of the supplied bulk drug substance in various physiologically acceptable aqueous and certain water miscible and least-toxic organic solvents.

2. Carryout physicochemical studies to characterize molecules including but not limited to solubility and stability profiles of the supplied bulk drug substance.

3. Develop approaches for intravenous, oral, and other delivery routes of drugs exhibiting inadequate solubility, stability, and/or bioavailability depending on the need of the Program in collaboration with the P.O.

4. Develop if necessary suitable stability-indicating assays to detect the active drug substance subject to a variety of experimental conditions including the formulation *per se*, heat, light, oxygen, and other parameters.

5. Prepare kinetic profiles to predict the stability of the drug substance in various physiologically acceptable aqueous vehicles and certain organic solvents as determined by NCI. Determination of pKa and partition coefficient of drug substance may be required.

6. Apply the solubility and stability enhancement approaches when needed to prepare experimental dosage formulations on small scale for subsequent therapeutic and toxicological

evaluation by NCI in animals. Pack, label, and ship the experimental products according to instructions provided by the Government.

7. Evaluate the experimental dosage form under simulated use conditions, i.e., completeness and clarity of the constituted solution after freeze drying, stability of this solution *per se* and after dilution with intravenous fluids in glass bottles and in polyvinyl chloride (pvc) bags and other suitable containers or bags for intravenous administration.

8. Carry out a short-term stability study of the finished dosage form under accelerated stability condition at 50^{O}C, 37^{O}C, 25^{O}C, and under refrigeration condition as needed and directed by the Government in collaboration with P.O. per Program needs.

9. Depending on the Program needs and/or agent under investigation, it may be necessary to study and develop different types of dosage forms such as controlled release or targeted delivery systems as well as dosage forms for different routes of administrations. If the expertise or capabilities are not available to the offeror, they shall acquire the cooperation of experts or consultants with approval by the Project Officer.

10. The contractor may also be asked by P.O. to develop other dosage forms like controlled release or targeted delivery system as well as dosage forms for different route of administration other than parenteral. The contractor thus should have the capability to evaluate the bioavailability and/or effectiveness of the drug in the said formulation to be able to use the result in optimization of the said delivery system.

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 start date is on or about August 21, 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/ . Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:

In event an RFP is issued, the NAICS code is 325412 and a size standard of 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 Key Personnel's qualifications for leading the project and the project teams ability to:

    - Development of parenteral dosage forms for intravenous use;
    - Development of stability indicating methodology;
    - Methods to improve drug solubility;
    - Development of other dosage forms or delivery systems;
    - Freeze drying of pharmaceutical products.

2. Document scientific rationale, ingenuity, and thoroughness of the proposed approach;

3. Demonstrated suitability of the proposed formulation approaches for intravenous administration;

4. Document the Quality and suitability of the facility, the Availability of the equipment for the performance of this work and the Suitability of the laboratory layout for the efficient development and production of experimental dosage units;

5. Document the adequacy of organization's experience in the development of pharmaceutical dosage forms, Quality and suitability of the general safety program, and the adequacy of program for disposal of chemical and hazardous waste;

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. All pages must be numbered including attachments, resumes, charts, etc.

2. **Deliver Point**:

   All capability statements sent in response to this Small Business Sources Sought notice must be submitted electronically (via email) to Andrea Spinelli, Contract Specialist, at spinella@mail.nih.gov with a cc 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-27003-10. Facsimile responses will not be accepted.

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

   Electronically submitted tailor capability statements are due no later than 2:00 PM (Eastern Prevailing Time) on Wednesday, November 16, 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).