

## 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 them with the requirement of this project; failure to do so will be at your firm's own risk.

### **Background:**

The Developmental Therapeutic Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) is involved in discovery and development of new therapeutic agents for treatment of cancer. Molecules for development enter the system under various mechanisms such as NCI Experimental Therapeutics Program (NExT) and Chemical Biology Consortium (CBC). The current contract provides the NCI with pharmaceutical development and production of oral and topical dosage forms for use in clinical trials.

### **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 one award may result from the issuance of the RFP.

## **Project Requirements:**

The Contractor shall furnish services, qualified personnel, material, and a complete, ongoing, and fully operational facility including all necessary equipment for all aspects of the production and analytical testing of the final product. The active pharmaceutical ingredient (API) will in most cases be supplied by the NCI. The dosage forms will include but not be limited to tablets, enteric-coated tablets, capsules, soft gelatin capsules, liquid filled hard gelatin capsule, oral powders, oral solutions, gel, cream and ointment. The facility and equipment shall conform to current Good Manufacturing Practices (cGMP) set forth by the FDA. Manufacturing activities could be sub-contracted if the Offeror does not have manufacturing capability of the soft gelatin capsules and topical dosage forms.

In addition, the Contractor shall provide adequate analytical instrumentation and pharmaceutical equipment to perform complete quality control evaluation of the formulated drug products.

### **1. Formulation Studies**

All new assignments may require pre-production evaluation such as preparation of formulation, adoption of stability-indicating assay or development of such assay, accelerated stability studies, process optimization and compatibility studies with excipients commonly used in the manufacture of oral and topical products. Information on chemical purity, analytical methods and some preliminary solubility data of the API will be provided if available at the time of the new assignments.

### **2. Production of Oral and Topical Dosage Forms**

The Contractor shall manufacture batches of drug products intended for the use in clinical trials. Validated Standard Operating Procedures (SOP) for all phases of production and compendial testing should be available to the Offeror at time of application. In case of capsules or tablets, batch sizes will range from several hundred units to as many as 50,000. In case of topical dosage forms, the batch size may be in the range of 50-1,000 units

Each written assignment will specify a dosage form, strength, batch size, and packaging size unless work is needed during the course of preparation of the formulation.

### **3. Quality Assurance**

The Contractor shall perform quality control testing of all components used in the formulation as well as the finished products. The testing shall include an identity of the API. Other tests such as purity of the API may be required to assure conformance with the previously obtained independent analytical results. All applicable compendial and other pharmaceutical testing for excipients shall be required.

Quality control evaluation of the finished drug products shall be required to assure conformance to the NCI specifications. In addition to the testing required for oral and topical dosage forms in

the current United State Pharmacopoeia (USP), the testing for the specifications may consist of the following as determined by the Contracting Officer's Representative (COR):

Oral Dosage Forms	Topical Dosage Forms
1) Identity	1) Identity
2) Assay and Impurities	2) Assay and Impurities
3) Content Uniformity	3) Content Uniformity
4) Dissolution	

The Contractor shall be responsible for Quality Assurance of products manufactured by the Sub-Contractors and shall provide detailed plans for monitoring sub-contract work.

4. Packaging, Labeling, Storage and Shipment of Finished Products

All finished products shall be labeled and packaged according to specifications supplied by the COR. Label preparation may be subcontracted, but labeling shall be performed on the contract site. All products shall be sent directly to the NCI's designated storage facility upon release and to arrive within two (2) days under appropriate storage conditions.

**Anticipated Period of Performance:**

It is anticipated that the award from this solicitation will be an IDIQ contract with cost plus fixed fee task orders. The duration of the contract will be five (5) years. The anticipated start date is on or about July 1, 2015.

**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:**

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:

**A. Staff Capabilities and Qualification**

- (1) Suitability and adequacy of the Project Director (PD) and Co-Project Director's (Co-PD) experience and qualifications. It is anticipated that PD and Co-PD will be

responsible for product development and production aspects of the contract. A Ph. D in Pharmaceutics, chemical engineering or chemistry or the equivalent in education and related experience is required.

- (2) Suitability and adequacy of the other personnel as to experience and qualifications to perform formulation development, product manufacturing, quality control and quality assurance. Manufacturing personnel should possess a BS degree such as pharmacy, chemistry, biology or equivalent experience/education.
- (3) Availability of the project team members.

**B. Facilities and Equipment**

- (1) Availability, adequacy and conformance of the proposed facilities and equipment to perform the functions of this contract as described in the Scope of Work and Technical Proposal Instructions. The proposed facility should have the capacity to produce thirty (30) liters of semisolids or liquid products and one hundred thousand (100,000) units of solid dosage forms such as tablets or capsules.
- (2) Availability of back-up equipment.

**C. Understanding the Project and Technical Approach**

Awareness and Adequacy for:

- (1) Possible approaches to resolve problems and difficulties in oral and topical formulation process.
- (2) Problems in scale-up from pilot to production size batches.
- (3) If needed, development and validation of necessary analytical procedures including quality control procedures.
- (4) Special handling procedures necessitated by potentially toxic antineoplastic agents for protecting individuals from inadvertent exposure.
- (5) Standard Operating Procedures for production, in-process testing, routine maintenance and validation of production and analytical equipment.

**D. Organizational Support and Experiences**

- (1) Overall organizational experience in the process of production, quality assurance, quality control, testing, packaging and labeling of oral and topical dosage forms under cGMP conditions for clinical use and be registered with the Food and Drug Administration (FDA) as a pharmaceutical manufacturing entity.

- (2) Organizational capability for handling and scheduling development and production assignments illustrated by the number of years in business and the number of projects performed each year on average.
- (3) Organizational priority to be given to the NCI projects.
- (4) Adequacy of safety measures.

**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 Heidi Crawley, Contracting Officer at [crawleyha@mail.nih.gov](mailto:crawleyha@mail.nih.gov) in MS Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-SBSS-TSB-57002-05. Facsimile responses will not be accepted.

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

Electronically submitted tailor capability statements are due no later than 2:00 PM (Eastern Prevailing Time) on Wednesday November 5, 2014. 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).