

SOURCES SOUGHT NOTICE NO. SS-NCI-TSB-2007-39

"Development and Production of Parenteral Dosage Forms for Clinical Studies"

This Source Sought Notice (SS) 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 (NCI).

The purpose of this SS is to identify qualified small businesses concerns including: 8(a), HUBZone, or Service-Disabled Veteran-owned business concerns 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 nor otherwise pay for the preparation of any information submitted. As a result of this Sources Sought, 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 Sources Sought or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

The National Cancer Institute is seeking qualified small businesses including 8(a), HUBZone, or Service Disabled Veteran-owned business concerns to develop and produce pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer. Data obtained from any contract that may be awarded will: 1) be used to support IND applications submitted by the National Cancer Institute to the U.S. Food and Drug Administration as well as foreign agencies, 2) be provided to other NCI contractors engaged in large scale dosage form manufacture and analytical evaluation of these dosage forms and 3) be provided to physicians, pharmacists, nurses, and other medical personnel handling these products in a clinical setting.

Capability Statements shall demonstrate an understanding of the development and production of pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer. If a Request for Proposals (RFP) is issued following this Sources Sought announcement, offerors will need to demonstrate, at the time of proposal submission, that they are registered with the Food and Drug Administration (FDA) as a pharmaceutical manufacturing facility for sterile products. **Tailored Capability Statements for this requirement** shall address the following four (4) areas: 1) technical approach, 2) personnel; 3) facilities and equipment and 4) corporate experience with similar projects.

1. A detailed Technical Approach that demonstrates a clear understanding of the draft SOW with discussions of a) formulation development; b) production of parenteral dosage forms; c) quality assurance and evaluation and d) packaging and labeling of finished products. Standard Operating Procedures used in the preparation and manufacture of dosage forms should be described as well as Standard Operation Procedures for protecting personnel from cytotoxic agents being formulated and quality control tested.

2. Personnel described must have experience with parenteral product development, especially freeze-drying, as well as expertise in the areas of sterile emulsions, liposomes and microdispersions. In addition, staff should possess experience with a variety of analytical instrumentation and the development of stability indicating assays.
3. A description of the facility that will be directly utilized and available for this proposed project, including laboratory, equipment and storage areas, should be provided. It is anticipated that the following equipment will be required to perform the Statement of Work and the availability of this equipment should be described:

A. Production Equipment

- Ampuling Equipment
- Vial Washing Facilities
- Autoclave (state capacity) and approved water for injection holding and distribution system
- Hot air sterilizer (state capacity)
- Automated filling equipment
- Production freeze drier(s) (state capacity)
- Sterilizing filtration equipment (state size and capacity)
- Compounding tanks (state capacity)
 - Sterile preparation area
 - Labeling and packaging equipment
 - Inspection station
 - Emergency support system for freeze drier(s)
 - Molecular filtration apparatus for removal of
 - pyrogens and/or particulates

B. Analytical and Development Equipment

- High performance liquid chromatograph (HPLC with variable wavelength detector and/or diode array detector, Evaporative Light Scattering Detector)
 - Recording ultraviolet-visible spectrophotometer
 - pH meter
 - Karl Fischer water analyzer
 - Water bath for solubility/stability studies
 - Infrared spectrophotometer
 - Pilot freeze drier (1 sq. ft. minimum shelf capacity)
 - Paper and thin layer chromatography jars
 - Melting point apparatus
 - Analytical balance
 - Molecular filtration equipment for removal of pyrogens
4. The description of your firm's corporate experience with similar projects should include your firm's general background, experience, and qualifications particularly with projects involving development and production of specialty parenteral formulations. A special notation should be made of similar or related programs performed for the Government including documentation with reference to the applicable contract numbers and the supervising agencies.

A copy of the draft Statement of Work (SOW) pertaining to this requirement, which is subject to revisions, may be accessed at Attachment 1 to this Sources Sought or it may be accessed on the NCI Office of Acquisitions External Website at URL: <http://rcb.nci.nih.gov/> Once there, click on Current Requests for Proposals. Under the section entitled Sources Sought, click on number SS-NCI-TSB-2007-39 entitled, *"Development and Production of Parenteral Dosage Forms for Clinical Studies"*. Interested parties are expected to review this notice and the draft SOW to familiarize yourself with the requirements of this project; failure to do so will be at your firm's own risk.

Interested qualified small business organizations should submit a **tailored capability statement for this requirement** not to exceed twenty (20) single sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the ability to perform the aspects of the notice described above and in the draft SOW. All proprietary information should be marked as such. Responses will be reviewed only by NIH personnel and will be held in a confidential manner. In the event an RFP is issued, North American Industry Classification System (NAICS) code **541710** with a size standard of 500 employees is being considered.

Capability statements are due no later than **3:00 p.m.** eastern prevailing time on **August 17, 2007**. Please submit one (1) original and three (3) copies of your response to:

If hand-delivered or delivery service

Theresa H. Shroff, Contracting Officer
Office of Acquisitions
National Cancer Institute
Building 244, Room 102
Fort Detrick
Frederick, Maryland 21702-1201

If using U.S. Postal Service

Theresa H. Shroff, Contracting Officer
Office of Acquisitions
National Cancer Institute
P.O. Box B, 244 Miller Drive, Room 102
Fort Detrick
Frederick, Maryland 21702-1201

NOTE: Fort Detrick is a secure military base. Couriers delivering proposals must use the 7th Street (Main Entrance) to gain access to Fort Detrick. It is recommended that you contact Theresa Shroff (301-228-4223) to schedule in advance a specific time in order to deliver your proposal. If Ms. Shroff is not available, please call 301-228-4228.

Facsimile responses will not be accepted. Electronic responses, via e-mail, may be sent to ts144t@nih.gov. Electronic submissions must be in WordPerfect or Microsoft Word. All responses must be received at NCI by the specified due date and time in order to be considered.

Point of Contact

Theresa H. Shroff, Contracting Officer, Phone: 301-228-4223; e-mail ts144t@nih.gov