

**Sources Sought Notice No. SS-NCI-TSB 2009-3**

**Title: Development & Manufacture of Oral and Topical Forms**

The Source Sought Notice (SS) for the above title is for information and planning purposes ONLY and not a solicitation or an obligation on the part of the National Cancer Institute (NCI). The above title will identify qualified small businesses including 8(a), HUBZONE, or Service-Disabled Veteran-owned business concerns that are interested in this requirement and capable of performing the work required for the Development & Manufacture of Oral and Topical Forms. The NAICS code for this topic is Number 325412. The NCI does not intend to award a contract on the basis of responses nor otherwise pay for the preparation of any information submitted. However, the NCI may issue a Request for Proposal (RFP) based on the responses. THERE IS NOT A SOLICITATION AVAILABLE AT THIS TIME. In the event a requirement for this title should materialize, a claim against NCI shall not arise as a result of a response to this SS title or the NCI's use of such information as either part of the evaluation process or in developing specifications for any subsequent requirement. Additionally, if the requirement is fulfilled, it is anticipated that three (3) cost-reimbursement, completion type contracts would be awarded for a period of five (5) years with an option for yearly extensions up to two (2) additional years.

The NCI is seeking qualified small businesses including: 8(a), HUBZone, or Service Disabled Veteran-owned business concerns to provide support to NCI's Pharmaceutical Resources Branch (PRB), Development Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD) in discovery and development of new therapeutic agents for treatment of cancer. Molecules for development may fall under several program departments, such as "Drug Development Committee (DDG)," "Rapid Access to Intervention Development (RAID)," or "Joint Development Committee (JDC)." Capability Statements shall demonstrate an understanding of all task specified in this Draft Statement of Work (DSOW). Tailored Capability Statements for this requirement **MUST** address the following **Mandatory Qualification Criteria:**

1. Drug products provided by the contractor are used for clinical trials in humans under an Investigational New Drug Application (IND) submitted to the United State Food and Drug Administration (FDA). Therefore, it is essential that an Offeror's manufacturing facilities must be in compliance with Good Manufacturing Practices (cGMP) set forth by the FDA. The clinical products to be produced in this contract should be manufactured under the cGMP in order to comply with the FDA regulations.
2. The Offerors must be registered with the FDA as a pharmaceutical manufacturing facility. The Offeror should show documented proof of routine FDA inspection (s) within the last 2 years. This requirement shall be met at the time of proposal submission. Moreover, the Offeror must be in compliance with FDA requirements during the entire course of the contract performance. In this regard, the Awardee shall notify the Project Officer of any outstanding FDA findings (FDA form 483) resulting from routine inspections and provide a proposed timetable for corrective

action to be enacted during the course of the contract performance. The Offeror must be in compliance with FDA guidelines for manufacturing oral and topical dosage forms for human use at the time of submission.

The following four (4) technical evaluation criteria in the following Areas (personnel, facilities and equipment, understanding the project and technical approach) will be used to determine technical acceptability.

1. **Personnel** – The Principal Investigator (PI) and Co-Principal Investigator’s (Co-PI) experience and qualifications for product development.
2. **Facilities and Equipment** – The availability, adequacy and conformance of the proposed facilities and equipment to perform the functions as described in the Scope of Work and Technical Proposal Instructions.
3. **Understanding the Project and Technical Approach** – Ability to resolve problems in oral and topical formulation development. Resolving difficulties associated with scale up to pilot production size batches. If required, developing and validating necessary analytical procedures including quality control procedures. Compliance with all federal and state laws dealing with toxic antineoplastic agents is required.
4. **Organizational Support and Experience** – Overall organizational experience in the development, production, quality assurance, quality control, testing, packaging and labeling of oral and topical dosage forms. DESCRIPTION OF WORK

### **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 manufacture and analytical testing of oral and topical dosage forms. The dosage forms will include but not be limited to tablets, enteric-coated tablets, capsules, soft gelatin capsules, oral powders, oral solutions, gel, cream and ointment. The facility and equipment shall conform with current Good Manufacturing Practices (cGMP) set forth by the FDA. Manufacturing activities could be sub-contracted if offeror does not have manufacturing capability of the soft gelatin capsules and topical dosage forms.

The Contractor shall provide all materials used in the manufacturing, testing, packaging and labeling of the formulated oral and topical drug products unless provided by the NCI. The active pharmaceutical ingredient (API) will in most cases be supplied by the NCI. In addition, the Contractor shall provide adequate analytical instrumentation and pharmaceutical equipment to perform complete quality control evaluation of the formulated drug products. Such equipment include the in-house capability to perform gas liquid chromatography, high performance liquid chromatography, ultraviolet and infrared spectroscopy, pH and moisture determination, dissolution, etc.

#### **A. Formulation Studies**

All new assignments shall require pre-production evaluation such as preparation of formulation or adoption of stability-indicating assay, accelerated stability studies, process optimization and

compatibility studies with excipients commonly used in the manufacture of oral and topical dosage forms. 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. The NCI will supply the API in most cases and the Contractor shall be responsible for acquisition of other supplies for the preparation works including analytical reagents, excipients, containers/closures and labels.

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

The Contractor shall manufacture batches of oral and topical drug products intended for the use in clinical trials. Validated Standard Operating Procedures (SOP) should be placed for all phases of production and compendial testing. 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. The Contractor shall provide excipients, container/closure systems and labels. The bulk drug substance will be supplied by the NCI unless the project Officer directs the Contractor to procure it from an approved source. 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.

#### **C. Special Dosage Forms**

Production of certain dosage forms such as soft gelatin capsules and topical dosage forms may not be available at the offeror's facility. In that case, the Contractor may utilize Sub-Contractors with the approval of both the Project Officer and Contracting Officer.

#### **D. 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 other components used in the formulation shall be required. Attributes for in-process testing for each dosage form shall be developed during the pre-production work and be performed during the production of the final products.

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 Project Officer:

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	

Other tests may be assigned by the NCI when necessary. The Contractor shall be responsible for Quality Assurance of products manufactured by the Sub-Contractors and shall provide detailed plans for monitoring sub-contract works.

**E. Packaging, Labeling, Storage and Shipment of Finished Products**

All finished products shall be labeled and packaged according to specifications supplied by the Project Officer. Label preparation may be subcontracted, but labeling shall be performed on the contract site. Finished products shall be stored at the labeled storage condition until released to the NCI. 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. In some instances, an emergency drop shipment of the products may be required directly to a clinical investigator or to the NCI storage Contractor.

**Capability statements**

Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed 20-single spaced pages (including all attachments, resumes, charts, etc.) presented in single-spaced and using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described. 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, as well as the eligible small business concern's name, point of contact, address, phone number and DUNS number.

**Capability statements are due no later than March 16, 2009, at 2:00 PM EDT.**

Please submit **one** (1) original and **three** (3) copies of your responses to:

**POSTAL ADDRESS:**

MaryAnne Golling  
Contracting Officer  
Treatment and Support Branch  
Office of Acquisitions  
National Cancer Institute at Frederick  
Post Office Box B  
244 Miller Drive, Room 118  
Fort Detrick  
Frederick, Maryland 21702-1201

**COURIER ADDRESS:**

MaryAnne Golling  
Contracting Officer  
Treatment and Support Branch  
Office of Acquisitions  
National Cancer Institute at Frederick  
244 Miller Drive, Room 118  
Fort Detrick  
Frederick, Maryland 21702-1201

All responses must be received at NCI by the specified due date and time in order to receive consideration.

**Any questions regarding this notice must be in writing and received by:  
Friday, March 13, 2009, at 2:00 PM EDT.**

**POINTS OF CONTACT:**

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Contract Specialist  
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MaryAnne Golling  
Contracting Officer  
Voice: (301) 228-4215  
Email: [gollingm@mail.nih.gov](mailto:gollingm@mail.nih.gov)

**Important Note:**

Capability statements must address the two(2) mandatory qualification criteria listed above.

**Disclaimer:**

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response to this notice. 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 organization's 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 synopsis and solicitations MAY be published in the Federal Business opportunities. Respondents will be added to the prospective Offerors list for any subsequent solicitation. However, responses to this notice WILL NOT be considered as an adequate response 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 information.