Notice Number: HHS-NIH-NCI-SBSS-ETSB-01010-03

Title: Regulatory Support for Clinical Trials of Therion Produced Vaccines

General Information:
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 they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the 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.

The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information submitted.

Background:
This action is a recompetition of Contract No. HHSN261200800001C awarded on a sole source basis to Mary Lou Horzempa. This work is required to continue on-going clinical trials until additional Cooperative Research and Development Agreements (CRADA) are reached with new NCI partners.

The Laboratory of Tumor Immunology and Biology (LTIB) is proposing to contract for consulting and professional services to support on-going and future clinical studies of recombinant poxvirus vaccines manufactured by the former Therion Biologics Corporation (Therion). These vaccines were developed jointly by LTIB and Therion under a longstanding Cooperative Research and Development Agreement (CRADA) to treat various cancers, including prostate cancer. Therion was responsible for (1) the generation and analysis of the recombinant viruses, (2) the manufacture and testing of virus stocks and vaccine product lots under Current Good Manufacturing Practices (CGMP), and (3) the preparation, submission, and maintenance of regulatory submissions containing all Chemistry, Manufacturing, and Control (CMC) information required by the Food and Drug Administration (FDA) for approval to conduct clinical trials of these vaccines. Therion closed abruptly in November, 2006. A new CRADA has been set up with Bavarian Nordic Immunotherapeutics (BNIT), to provide the CMC support necessary to continue the clinical research in the prostate cancer program; transition to this new CRADA partner is in progress. Additional CRADA(s) will also be established to continue the other Therion vaccine programs. At the same time, the integrity and stability of the vaccine materials must be continuously preserved and monitored, and the Investigational New Drug Applications (INDs) and related Master Files (MFs) filed by the Cancer Therapy Evaluation Program (CTEP) with the FDA must be supported and updated as required. This contract provides the scientific and regulatory expertise necessary to maintain the CMC status of the Therion vaccines in good standing with the FDA and enable the continuation of the associated clinical studies sponsored by CTEP.

Purpose:
This purpose of this project is to provide consulting and professional services to support on-going and future clinical studies of vaccines manufactured by Therion.

As a result of this Sources Sought 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 claims against NCI shall arise as a result of a response to this Sources Sought Notice or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

Project Requirements:
The Contractor shall provide the following tasks: monitoring of stability testing of vaccines, vaccine inventory management, maintenance of regulatory documentation including, Investigational New Drug applications for vaccines developed under a CRADA with Therion and assistance in transitioning vaccine development to a third party partner. Any Contractor performing this work must have knowledge of assay procedures and Investigational New Drug applications. In addition, the Contractor must monitor transfer and inventory of current vaccines from a third party contractor to a Government repository; this requirement will allow the continuity of the vaccine clinical trials within the NCI and to continue with the current schedule of these clinical trials. The Contractor shall provide technical assistance in the preparation of any new lots of vaccines produced using the original seed stocks developed at Therion.

Anticipated Period of Performance:
The anticipated period of performance, inclusive of all options, for this proposed contract is 03/01/2010 through 02/28/2013. The contract will consist of a one (1) year base period (03/01/2010 – 02/28/2011) and if exercised, a one (1) year option period (03/01/2011 – 2/29/2012) and two (2), six (6) month option periods (03/01/2012 – 08/31/2012) and (09/01/2012 – 02/28/2013).

Description of Information to be included in the Capability Statement:
Tailored capability statements shall demonstrate a clear understanding of all tasks specified in the Project Requirements section. Specifically, tailored capability statements for this requirement shall demonstrate the ability to provide knowledgeable professionals and demonstrate a technical understanding.

NAICS Code and Size Standard:
In the event an RFP is issued, the North American Industry Classification System (NAICS) code 541690 with a size standard of $7 million is being considered.

How to Submit a Response:

1. **Page Limitations:**
   Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed 10 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. All proprietary information should be marked as such. 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. Responses will be reviewed only by NIH personnel

and will be held in a confidential manner.

2. **Due Date:**
   Tailored capability statements are due no later than 3:00 PM (Eastern Prevailing Time) on August 12, 2009.

3. **Number of Copies and Delivery Point:**
   Please submit one (1) electronic copy of your response to bainerin@mail.nih.gov.

Point of Contact:
Inquiries concerning this Notice may be directed to:
Erin Bain, Contract Specialist
Email: bainerin@mail.nih.gov
Phone: 301.435.3814

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 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 solicitation 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).