This Notice is a revision of the Sources Sought Notice previously posted on January 5, 2009 and is intended to provide updated information regarding the requirement. Please be advised that the notice dated 1/5/2009 with a response date of 1/21/2009 is the OLD NOTICE and is no longer relevant.

Sources Sought Notice No: SS-PCPSB-5003-47
Amendment Number One
Title: "Centralized Chemopreventive Agent Repository and Chemistry Support"

The Division of Cancer Prevention (DCP) of the National Cancer Institute (NCI) is planning to award a contract for a centralized chemopreventive agency repository with multiple functions and duties. This Sources Sought notice (SS) is for informational and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute.

The purpose of this SS is to locate QUALIFIED SMALL BUSINESS CONCERNS with the ability to perform the requirements of the program. Small Business Concerns include: Small Disadvantaged Businesses (SDB), Woman-owned Small Businesses (WOSB), Historically Underutilized Business Zone (HUBZONE) Small Businesses, Veteran-Owned Small Business (VOSB), Service-Disabled Veteran-Owned Small Businesses, and 8(a) Small Business. ONLY SMALL BUSINESSES SHOULD RESPOND TO THIS NOTICE.

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

The DCP is seeking capability statements from all eligible Small Businesses as stated above, under NAICS Code: 541690 with a size standard of $7 million dollars.
The purpose of the acquisition is to provide services to support many different agent development functions critical to chemoprevention research. These functions are generally described as sourcing, acquiring, documenting, storing, quality testing , custom manufacturing, packaging and labeling, distributing and tracking both pre-clinical investigational agents for basic research and clinical supplies for human clinical trials.

1) The Core Competencies required include cost estimation, agent receiving, specification setting, analytical testing, material acceptance and release, packaging and labeling, stability testing, proper environmental storage, shipping domestically and abroad, inventory tracking of clinical trial materials, agent returns and destruction or disposal of investigational agents and clinical study supplies. All information to support regulatory filings to health authorities, scientific reports for research documentation and manuscript publication will be maintained by the contractor and provided to DCP, when requested.

If the contract requires specialty [subcontracted] services for the timely development of agents identified through DCP programs (e.g., the DCP RAPID program), A well-organized and effective subcontracting administrative unit will be needed.

2) An offeror's facility must have sufficient space for: storage of pre-clinical agents (estimated at 5,000 sq. ft. of useable space); storage of clinical study supplies (estimated at 5,000 sq. ft.of useable space); a staging/quarantine area; separate shipping and receiving rooms; and, space devoted to an analytical chemistry unit (estimated at 5,000 sq. ft.) with a detached weighing area. The space must include areas for refrigerated and other environmentally-controlled storage conditions (e.g., light protection, humidity controlled cabinets - approximately 500 sq. ft.).

3) A comprehensive and continuously updated computerized logistics management system containing inventory movements, quantities on hand, expiration or re-test information, Certificates of Analysis and analytical testing results, on all materials, must be made available electronically to the Project Officer/Contracting Officer's Technical Representative on demand through a secure, password-protected, DCP-dedicated server.

4) The Contractor will be required to demonstrate experience and competency in domestic and international shipping of pharmaceuticals, especially through U.S. and foreign Customs, the FDA, and other Health Authorities in accordance with applicable regulations. The Contractor must have experience in obtaining a Quality Persons Determination for agents shipped into the European Union.

CAPABILITY CRITERIA – Capabilities will be judged based on the following criteria:

1. History of key personnel having prior experience as a team in core competencies including providing supplies for clinical trials.
2. Proof of adequate facility space
3. Demonstration of a working computerized logistics management system
4. Demonstrated experience with international shipping of pharmaceuticals

AT THIS TIME, ONLY CAPABILITY STATEMENTS FROM INTERESTED, QUALIFIED SMALL BUSINESSES ARE BEING REQUESTED. THIS NOTICE IS NOT A REQUEST FOR PROPOSALS.
Capability Statements must specify the offeror's business size and type, and demonstrate similar work that has been performed in the past five years and the dollar value of that work. The required service is defined as NAICS code 541690 with a size standard of $7 million dollars. Small businesses that believe that they have the ability to satisfy all of the above stated competencies, and who meet the stated size standards should be limited to no more than fifteen (15) pages (including all attachments, charts, etc.) using a 12 point font size minimum. All proprietary information should be marked as such. The capability statement should include an indication of current certified small business status; this indication should be clearly marked on the first page of the statement (preferably placed under the eligible small business concern's name and address). Responses will be reviewed only by NIH personnel and will be held in a confidential manner. If responses indicate the likelihood of satisfactory competition among qualified businesses, the anticipated solicitation will be restricted to small businesses only.

All capability statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to Dianne M. Gray, Contracting Officer Representative, at graydi@mail.nih.gov in either MS Word or WordPerfect, or ADOBE Document Format (PDF), by September 11, 2009, 3:30PM Eastern Time. Questions regarding this requirement must be submitted in writing and directed to Dianne M. Gray at the above email address before the closing date of this notice. All responses must be received by the specified due date and time in order to be considered.