DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 16, 2006

Ms. Anu K. Mittal
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Mittal:

The National Institutes of Health (NIH) appreciates the opportunity to provide additional comments on the U.S. Government Accountability Office (GAO) report entitled "Small Business Innovation Research: Information on Awards Made by NIH and DoD in Fiscal Years 2001 Through 2004" (GAO-06-565).

The GAO report does not address NIH's central concern, which is that the Small Business Administration's (SBA) eligibility rules for Small Business Innovation Research (SBIR) grants are unduly restrictive and still exclude some business concerns that may contribute to important medical research, particularly in the biotechnology sector. NIH believes that the impact of the current eligibility rules presents a significant roadblock in our technology development pipeline and ultimately in the speed in which important products to improve health are brought to market.

Although the GAO report provided data on the role of venture capital investments in the SBIR program, it did not make recommendations concerning eligibility for SBIR awards vis-à-vis venture capital ownership. However, the report provides useful information. It does note that "research in specific fields, such as biotechnology" is "relatively costly to conduct."

Biotechnology requires high, intense capital needs, in part because of the extensive regulatory requirements unique to this field (e.g., FDA approval). This arena of research requires significant investments by venture capital entities, many of which may not be majority owned by individuals or other businesses that meet SBA standards.

The world of biotechnology research by small innovative companies has undergone drastic changes in the last ten years. Today, the risk levels are higher, the "burn rate" for research funds is intensifying, and development times to bring nascent ideas to market are growing longer. Small biotechnology companies face ever-increasing demands for capital. In areas such as drug development, drug discovery, and therapeutics, less than one percent of the innovative, promising projects reach the marketplace.

These circumstances, among others, illustrate the unique challenges facing many start-up or early-stage biotechnology companies. Indeed, NIH is aware of small companies that must seek financing on multiple fronts, including substantial venture capital investments, to enable them to explore and develop new drugs, devices, and therapies to improve public health. Companies that receive such support often have some of the best proposals for new and creative early research. In NIH's view, the SBA's individual ownership standards deny the opportunity for many small companies to conduct promising biomedical research under the SBIR program. For example, because of these standards, many small businesses are left out, especially some businesses that are majority owned by multiple venture capital firms, and that is the key reason for NIH's concerns about the SBA's eligibility rules.

NIH believes that a possible solution to the problem facing ineligible small businesses would be to expand eligibility to include small businesses that are owned and controlled, at least in part, by a single venture capital firm or multiple venture capital firms, provided that at least 51 percent of the small business is owned by U.S. individuals and/or venture capital firms that are owned no more than 49 percent by foreign business entities or individuals, and, provided further, that applicable small business affiliation standards are satisfied.

NIH is committed to ensuring that only *small* business concerns receive SBIR awards. To advance this goal, and ensure that NIH also meets its need to support deserving research and development that may contribute to important medical research, particularly in the biotechnology sector, NIH believes its proposed solution offers a well-tailored and defensible means to resolve the problem.

Sincerely,

Norka Ruiz Bravo

Norka Ruiz Bravo, Ph.D.
Deputy Director for Extramural Research, NIH