



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



JAN 25 2013

The Honorable Claire McCaskill
Chairman, Subcommittee on Contracting Oversight
Committee on Homeland Security and Government Affairs
United States Senate
Washington, DC 20510

The Honorable Renee Ellmers
Chairwoman, Subcommittee on Healthcare and Technology
Committee on Small Business
House of Representatives
Washington, DC 20515

Dear Chairpersons:

The enclosed information responds to your letters dated November 21, 2011, and December 14, 2011, requesting that the Office of Inspector General review the process by which the Department of Health and Human Services (HHS) awarded a sole-source, small-business set-aside contract to SIGA Technologies, Inc. (SIGA), for the development of a smallpox treatment.

Each of you expressed concerns about circumstances surrounding the award of the contract. Senator McCaskill raised questions regarding the reasonableness of the contract and Representative Ellmers expressed concerns about SIGA's small-business size status.

As outlined in my May 24, 2012, letter to you, we combined your requests and undertook a single review that is responsive to concerns raised in both letters. Specifically, we reviewed the contracting and award process used by HHS to award the contract to SIGA. We limited the review to the official contract files and related correspondence maintained and provided by the contracting officers and the HHS program officer. We also reviewed the Justification for Other Than Full and Open Competition and the sole source and small-business set-aside solicitation notices to determine whether HHS met Federal acquisition requirements for the contract. We did not determine whether there was a need for awarding the contract or whether the solicitation should have been restricted to small businesses.

Our review of the contract file documentation determined that the source selection executive board of the Biomedical Advanced Research and Development Authority directed the HHS contracting office to award a \$433 million sole-source contract to SIGA to develop and manufacture 1.7 million treatment courses of a smallpox antiviral drug to be delivered to the Centers for Disease Control and Prevention Strategic National Stockpile. The Justification for Other Than Full and Open Competition for the contract was authorized under Federal Acquisition Regulation 6.302-3(a)(2)(i), "Industrial Mobilization," and was documented, approved, and publicized in accordance with Federal laws, regulations, and guidance.

As shown in the enclosed “Acquisition Process Timeline,” the HHS Office of Acquisition Management, Contracts, and Grants (the contracting office) initially solicited the contract as a small-business set-aside award on May 11, 2009. However, when the contracting office proposed awarding the contract to SIGA on October 1, 2010, Chimerix, Inc., questioned the small-business status of SIGA and protested the award. On October 8, 2010, the contracting office submitted to the Small Business Administration a request that it determine the business size of SIGA. On November 5, 2010, the Small Business Administration determined that SIGA was not a small business. Subsequently, the contracting office obtained a removal of the small-business set-aside and opted to obtain the smallpox antiviral drug from a single source using the limited-source justification for industrial mobilization.

Our review of the official contract files and related correspondence maintained and provided by the contracting officers and the HHS program officer did not identify any violation of Federal statute or regulation in awarding the contract to a single source using the limited-source justification for industrial mobilization. We could not determine whether SIGA’s representation as a small business was made in good faith or whether SIGA knowingly misrepresented its size. Although an internal email from September 2010 stated that SIGA knew before the Small Business Administration determination that it was other than a small business, there was no evidence in the documents we reviewed that SIGA knew this at the time it submitted its bid for the small-business set-aside award.

If you have any questions, please contact me, or your staff may contact Chris Hinkle, Director of Congressional and Regulatory Affairs, at (202) 401-2206 or through email at Christina.Hinkle@oig.hhs.gov.

Sincerely,



Daniel R. Levinson
Inspector General

Enclosure

**ACQUISITION PROCESS TIMELINE
SIGA TECHNOLOGIES, INC., CONTRACT**

DATE	EVENT
07/21/2004	The President signed the Project BioShield Act of 2004, which authorized the Government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox, and other potential agents of bioterror.
12/23/2008	The Deputy Secretary of the Department of Health and Human Services (HHS) made a determination to include a smallpox antiviral drug as an appropriate countermeasure in the Centers for Disease Control and Prevention's Strategic National Stockpile.
01/21/2009	The HHS Office of the Assistant Secretary for Preparedness and Response approved the Biomedical Advanced Research and Development Authority's (BARDA) acquisition plan for a smallpox antiviral drug authorized under the Project BioShield Act. The approved plan called for a small-business set-aside procurement because HHS officials had determined that at least two small businesses would be willing to bid on the proposal.
02/05/2009	The Small Business Administration (SBA) approved the acquisition plan request for proposal as a small-business set-aside procurement.
03/11/2009	The HHS Office of Acquisition Management, Contracts, and Grants (the contracting office) issued a request for proposal for the BARDA requirement under solicitation number RFP-BARDA-09-35.
05/07/2009	SIGA Technologies, Inc. (SIGA), submitted its proposal.
05/13/2009	Chimerix, Inc. (Chimerix), submitted its proposal.
05/14/2009	The request for proposal closed; only SIGA and Chimerix submitted proposals.
05/18/2009	Chimerix submitted a protest to the contracting office alleging that improper contacts by SIGA with BARDA personnel violated the Procurement Integrity Act. Before an award, all communications must be directed only to the contracting office (41 U.S.C. § 2102).
06/22/2009	The contracting office denied Chimerix's 05/18/2009 protest after determining that there was no evidence that SIGA violated the terms of the request for proposal or the Procurement Integrity Act.

DATE	EVENT
06/26/2009	The HHS technical evaluation panel determined that the proposals from SIGA and Chimerix met all of the requirements of the request for proposal and each of their bids was in the competitive range anticipated by HHS.
07/07/2009	Chimerix submitted a protest to the contracting office questioning SIGA's small-business status.
07/14/2009	SBA rejected Chimerix's protest as premature because a successful offeror had not been named.
11/24/2009	<p>The contracting office determined that Chimerix did not meet criterion 2 (i.e., testing of the antiviral drug) of the original mandatory criteria-for-eligibility clause of the request for proposal and excluded the Chimerix bid from the competitive range.</p> <p>The contracting office advised Chimerix that any revisions to its proposal would not be accepted or considered.</p>
11/25/2009	Chimerix submitted a protest to the contracting office alleging Procurement Integrity Act violations, stating that its exclusion from the competitive range was made known to others before the contracting office notified Chimerix.
11/30/2009	Chimerix submitted a Freedom of Information Act request to HHS that asked for copies of all formal and informal communications between HHS and SIGA. (Documentation provided did not indicate whether the request was granted.)
01/06/2010	The contracting office issued Amendment 8 to the request for proposal, which deleted criterion 2 of the original mandatory criteria for eligibility.
01/15/2010	The contracting office reinstated Chimerix into the competitive range after HHS determined that Chimerix's initial technical and business proposal met the revised mandatory criteria for eligibility.
02/02/2010	<p>The contracting office denied Chimerix's protest of 11/25/2009 and gave as its reason that there was no evidence anyone had been provided information regarding Chimerix's exclusion from the competitive range.</p> <p>The contracting office requested revised proposals from SIGA and Chimerix because of the amount of time that had passed since the issuance of the original request for proposal.</p>
03/30/2010	The contracting office determined that the revised proposals from both SIGA and Chimerix were in the competitive range.

DATE	EVENT
06/01/2010	SIGA and Chimerix delivered final proposals to the contracting office.
09/28/2010	The contracting officer noted in an email to the HHS Office of General Counsel that SIGA's Chief Executive Officer stated that SIGA "... is not a small business; however, they were a small business at time of proposal submission." (The contracting officer's email stated that SIGA's Chief Executive Officer made this statement during a phone call regarding an unrelated matter.)
10/01/2010	The contracting office issued its notice of intent to award the contract to SIGA under the small-business set-aside request for proposal. The contracting office notified Chimerix, a small business and the only other offeror, that its proposal was unsuccessful.
10/08/2010	Chimerix submitted a protest, which stated that SIGA was not a small business. The contracting office forwarded the protest to SBA.
11/05/2010	SBA determined that SIGA was not a small business. SBA made this determination after reviewing applicable SBA guidance and SIGA documentation that outlined SIGA's relationships with other corporate entities.
11/10/2010	SIGA appealed the SBA determination.
11/17/2010	The contracting office posted a notice on the FedBizOpps Web site to determine whether there were any other small businesses interested in the revised request for proposal.
11/24/2010	Chimerix expressed interest in the revised request for proposal. (No other contractors expressed interest.)
12/13/2010	HHS signed a Justification for Other Than Full and Open Competition, which authorized the award of the contract to SIGA to develop a final drug product and manufacture 1.7 million treatment courses of its smallpox antiviral drug.
02/15/2011	SBA denied SIGA's appeal of the 11/05/2010 determination that classified SIGA as "other than small business."
02/16/2011	Under a separate "broad agency announcement," the contracting office awarded an unrelated "research and development" contract for \$24.8 million to Chimerix for the development of its smallpox antiviral drug.

DATE	EVENT
02/18/2011	The contracting office canceled the original request for proposal and notified SIGA that it would award SIGA a sole-source award under a new solicitation (RFP-11-100-SOL-00007), which included an option for 12 million additional treatment courses.
02/26/2011	SIGA submitted to the contracting office its revised proposal for solicitation RFP-11-100-SOL-00007.
03/09/2011	The BARDA source selection executive board signed a sole-source selection memorandum (Notice of Intent To Use Other Than Full and Open Competition) that identified SIGA as the successful contractor and notified the contracting office of its decision.
03/21/2011	Chimerix protested the sole-source award to SIGA.
05/03/2011	HHS amended the Justification for Other Than Full and Open Competition. The contracting office posted a special notice synopsis on the FedBizOpps Web site that stated its intent to award a sole-source contract to SIGA in accordance with Federal Acquisition Regulation 6.302-3(a)(2)(i), "Industrial Mobilization."
05/05/2011	The contracting office dismissed Chimerix's protest of 03/21/2011.
05/13/2011	The contracting office awarded the sole-source award to SIGA for \$433 million on the basis of the request for proposal in solicitation RFP-11-100-SOL-00007 (Contract HHS0100-2011-00001C). Chimerix filed a new protest questioning the addition of the option for 12 million additional courses. The contracting office issued SIGA a stop-work order.
06/09/2011	The House Committee on Oversight and Government Reform and the House Committee on Small Business issued to the Secretary a congressional inquiry regarding the procurement process for the development and manufacture of a smallpox antiviral drug.
06/24/2011	The contracting office modified SIGA's contract to delete the option for additional treatment courses.
06/27/2011	Chimerix withdrew its protest. The contracting office released SIGA from the stop-work order.