MAY 22 2007

TO: Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration

FROM: Daniel R. Levinson
Inspector General

SUBJECT: Emergency Response to Hurricanes Katrina and Rita: Audit of Food and Drug Administration's Award Process for a Contract With Cepheid (A-03-06-00542)

This report provides the results of our audit of the Food and Drug Administration's (FDA) award process for a contract with Cepheid of Sunnyvale, California. The audit is one of several reviews of procurements by FDA and other components of the Department of Health and Human Services (HHS) in response to Hurricanes Katrina and Rita in 2005.

BACKGROUND

Hurricane Relief Efforts

As a result of damage sustained during Hurricane Katrina, the New Orleans Department of Health evacuated its facility with little equipment and few supplies. Following the disaster, public health officials were concerned about the possible spread of infectious disease agents. The detection of these agents required sophisticated equipment and special reagent test kits. To assist the New Orleans Department of Health in detecting infectious disease agents, FDA issued a fixed-priced contract to Cepheid. The contract obligated Cepheid to provide reagent test kits. The contract, effective September 16, 2005, provided $79,500 for this purpose.

FDA's Office of Acquisitions and Grants Services was responsible for soliciting, negotiating, awarding, and administering the contract.

Federal Acquisition Regulations

The Federal Acquisition Regulation (FAR) defines a contract as a mutually binding legal relationship obligating the seller to furnish the supplies or services and the buyer to pay for them. It includes all types of commitments that obligate a Government expenditure of appropriated funds, including awards, job orders, letter contracts, orders, and bilateral contract modifications (FAR 2.101).

The FAR establishes the basic requirements for acquisitions by Federal agencies. The Health and Human Services Acquisition Regulation (HHSAR) implements and supplements the FAR and provides requirements that specifically govern the HHS contract process.

The FAR and the HHSAR provide, among other things, that HHS agencies award each contract to a responsible party (FAR 9.103(a)) and document compliance with requirements for full and open competition and the determination that the price was fair and reasonable (FAR 6.101(b) and 15.402(a)). Agencies also must develop a statement or description of the goods or services being requested (FAR 16.504(a)(4)(iii)).

Letter contracts may be used only for urgent needs. Unpriced orders, which must contain price ceilings, may be used only when it is impractical to obtain pricing. In addition, agencies must consider the appropriate contract type pursuant to guidance in FAR part 16. In certain situations, consideration must be given to small and minority businesses and local firms.

On September 8, 2005, recognizing the unusual and compelling circumstances created by Hurricane Katrina, the HHS Office of Acquisition Management and Policy issued a "Class Justification for Other Than Full and Open Competition and Waiver of Synopsis Requirements" (waiver). The waiver, which was effective until October 27, 2005, allowed HHS agencies to temporarily limit the actions taken to ensure full and open competition during the procurement of urgently needed items and services. For example, the extent of market research and other competitive procedures could be limited as considered necessary in the circumstances. For procurements valued at more than $100,000, the waiver required HHS agencies to ensure that their procurement records included a copy of the waiver, a note indicating compliance with the applicable limitations, and a signed statement that the award was made in response to the hurricane.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to determine whether FDA complied with FAR and HHSAR requirements during the award process involving Cepheid.

Scope

We limited our audit to the award process for FDA's contract HHSF2232000510387P, effective September 16, 2005, with Cepheid. We did not assess FDA's overall internal control environment. We also did not review contract performance or the acceptance and inspection of goods and services received.

We performed fieldwork at FDA's Office of Acquisitions and Grants Services in Rockville, Maryland, during May 2006.

Methodology

To accomplish our objective, we:

- reviewed FAR and HHSAR requirements,
- met with FDA officials to ensure an adequate understanding of FDA's actions during the award process and the basis for those actions, and
- examined the records of negotiation and other documentation related to the award of the contract to determine whether FDA followed FAR and HHSAR requirements.

We performed our audit in accordance with generally accepted government auditing standards.

RESULTS OF AUDIT

FDA complied with FAR and HHSAR requirements during the award process for contract HHSF2232000510387P with Cepheid. FDA awarded this contract under the waiver that limited actions necessary to ensure full and open competition. According to the procurement records, FDA had determined that an unusual and compelling urgency existed sufficient to solicit from a single source, Cepheid. Furthermore, the procurement records contained all documentation required by the waiver.

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This audit was conducted in conjunction with the President's Council on Integrity and Efficiency (PCIE) as part of its examination of relief efforts provided by the Federal Government in the aftermath of Hurricanes Katrina and Rita. As such, a copy of the report has been forwarded to the PCIE Homeland Security Working Group, which is coordinating Inspectors General reviews of this important subject.

If you have any questions about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-03-06-00542.