DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 4, 2010

The Honorable Charles E. Grassley
Ranking Member, Senate Committee on Finance
United States Senate
Washington, D.C. 20510-1501

Dear Senator Grassley:

On March 4, 2010, the Government Accountability Office (GAO) released a report entitled *Food and Drug Administration: Improved Monitoring and Development of Performance Measures Needed to Strengthen Oversight of Criminal Misconduct Investigations*. The report raises concerns about the oversight of the Office of Criminal Investigations (OCI) by the Food and Drug Administration (FDA or the Agency), in particular the lack of performance measures to assess OCI's success. FDA agreed with this finding and is currently developing meaningful performance measures for OCI, as part of an Agency-wide initiative. In addition, the Agency is implementing other significant efforts that address the issues GAO identified as well as more broadly enhance coordination, communication, and strategic alignment of public health priorities between OCI and other Agency components.

OCI has been successful in its declared mission "to conduct and coordinate investigations of suspected criminal violations . . . and to collect evidence to support successful prosecutions." From its inception in 1992 until the end of fiscal year 2009, OCI obtained 4,392 convictions that resulted in the imposition of $9.89 billion in fines and restitution and forfeited assets worth over $1 billion. Recognizing that opportunities exist to improve accountability and to better integrate OCI's work within the Agency, in August 2009, FDA formed a committee comprised of senior leadership, including the Centers, OCI, the Office of Chief Counsel, and the Office of the Commissioner to examine opportunities and develop recommendations to enhance coordination and strategic alignment between OCI and other Agency components. The committee made several recommendations.

The first recommendation was to improve procedures for information-sharing between OCI and other Agency components with the goal of enhanced alignment of criminal/regulatory priorities and activities. It is important for OCI to have the latest information from the Centers on emerging risks and regulatory policies and priorities. Similarly, the Centers need information from OCI on criminal activities and associated product risks so that the Centers and the Office of Regulatory Affairs can formulate effective regulatory policies and effectively allocate resources for inspections, risk communications, and regulatory activities, including civil enforcement.

FDA now has drafted procedures that will standardize information sharing between OCI and other Agency components and improve coordination within the Agency. Six months after these procedures have been adopted, FDA will assess the progress in implementing these new policies. Additionally, OCI is currently conducting outreach to the Centers and District Offices to better educate them about OCI's roles and responsibilities in protecting the public health and identifying potential criminal violations, and the process for making appropriate referrals.

Second, the committee recommended that FDA strengthen the mechanisms that are used to ensure that senior leaders share information and coordinate strategic priorities to align criminal enforcement and regulatory activities. FDA has identified best practices that will facilitate this information sharing and coordination, improve FDA's criminal and regulatory enforcement efforts, and strengthen the effectiveness of those Agency offices involved in FDA's enforcement efforts.

A third recommendation from the committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Criteria now have been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions.

Fourth, the committee recommended, consistent with the findings of a 2009 GAO report on FDA's oversight of clinical investigators, that the Agency enhance its debarment and disqualification procedures. In August 2009, FDA announced major changes to improve its debarment and disqualification processes to prevent non-compliant investigators from participating in new medical product development. These changes include increased staffing and centralized coordination to ensure that more rapid, transparent, and consistent actions are taken. In addition, FDA will enhance its procedures to support the development of debarment and disqualification actions, and we will clarify the circumstances under which such administrative actions may proceed concurrently with pending criminal investigations and prosecutions. The Agency also will take steps to ensure that sponsors involved in the testing and development of new medical products have ready access to information about FDA's debarment and disqualification actions. In addition, the FDA now is posting initiated and completed disqualification and debarment actions online.

Finally, the committee recommended that FDA improve the coordination of its response to cargo theft of FDA-regulated products, such as pharmaceutical and infant formula. Potential threats include counterfeiting, diversion, tampering, adulteration, misbranding, theft, and terrorist acts. Such risks require rapid and coordinated action from the Agency to ensure that the criminal investigation conducted by OCI is aligned with efforts by the Agency's regulatory experts to determine the public health impact and ways to mitigate that impact, as well to ensure that an appropriate public alert or notification is issued in a timely manner. The Agency is developing standard operating procedures for integrating activities involving

OCI and Center/Office components to ensure that FDA's regulatory response to cargo thefts is consistent and effective

Thank you for the opportunity to share this progress with you. We are committed to working with you to continue to improve the oversight and effectiveness of OCI. Please let us know if you have any questions.

Sincerely,

Margaret A. Hamburg

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs