DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 2 4 2010

The Honorable Joe Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Barton:

Thank you for your letter of October 21, 2009, cosigned by then-Ranking Member Greg Walden, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, regarding investigation by the Food and Drug Administration (FDA or the Agency) of alleged employee misconduct. As we noted in our December 29, 2009, interim response to you, this is an important topic and we appreciate your interest in the role of FDA's Office of Internal Affairs (OIA) in these investigations.

On February 17, 2010, Dr. Joshua Sharfstein, John Taylor, and I met with your staff, Alan Slobodin, to discuss your concerns. This letter is in follow up to our meeting.

At our meeting, we discussed apparent misunderstandings, evident from the narrative portion of your letter, about the dissolution of the 1998 Memorandum of Understanding (MOU) between OIA and the Department of Health and Human Services (HHS), Office of Inspector General (OIG). In 1998, FDA and OIG entered into an MOU delineating their respective roles and the procedures to be followed when investigating FDA employees. OIG withdrew from the MOU, effective March 30, 2008. Your letter indicates that the dissolution of the MOU resulted in OIG assuming primary investigative oversight for all potential criminal cases involving FDA employees, and caused a downsizing of OIA's investigative role. In fact, OIG always retained primary investigative authority over potential criminal violations by FDA employees, even when the MOU was in effect. Both during the existence of the MOU and since its dissolution, OIA has promptly notified OIG of every case that it has initiated (excluding routine motor vehicle accident cases), whether the allegations involved criminal or non-criminal conduct, and OIG has always retained the authority to join in any OIA investigation or assume the lead in the investigation without OIA involvement.

Also, your letter states that FDA's criminal investigators are not generally subject to investigations by OIA for allegations of non-criminal misconduct, resulting in an alleged disparity of treatment among FDA employees. You base your statement on a February 10, 2009, letter from FDA about the use of an outside contractor to assist FDA's Office of Criminal Investigations (OCI) with personnel matters. As we explained to your staff, we believe that our previous letter has created the mistaken impression that an outside contractor conducts non-

criminal investigations of OCI employees. In fact, OCI relies on OIA (and OIG, should it choose to become involved) to conduct its internal investigations, including allegations of non-criminal conduct. OIA investigates allegations of misconduct by OCI personnel when OIA's investigative expertise is needed to make factual determinations. Once the OIA (and OIG, when it has chosen to become involved) investigation of the alleged misconduct is complete, the outside contractor advises OCI and FDA on appropriate personnel actions, based on the contractor's expertise in such matters. FDA's handling of alleged misconduct by OCI employees is consistent with its approach for other FDA employees.

In your letter you also express concern about the use of FDA criminal investigators in FDA employee misconduct cases among employees described as "whistleblowers." We thought you would be interested in a recently implemented FDA policy that addresses this issue. FDA has had discussions with OIG, Special Investigations Unit, regarding situations where there is an allegation of criminal conduct against an FDA employee and that employee has a pending complaint against the Agency or an FDA employee alleging mismanagement, including waste, fraud, or abuse. In such cases, the criminal allegation will be referred to the OIG's Special Investigations Unit for appropriate handling and disposition. OIG's Special Investigations Unit will be the lead investigative agency. OIA's involvement will only come if asked by OIG, and, under those circumstances, only under the direction of the OIG's Special Investigations Unit. This policy has been in effect since February 16, 2010.

We have restated your questions below in bold, followed by our responses.

1. **Unlike other HHS agency employees, should FDA employees be subjected to investigations conducted by FDA criminal investigators for non-criminal allegations? If so, why and/or under what circumstances?**

Though the majority of cases investigated by OIA are non-criminal in nature, they nevertheless involve serious misconduct. Examples of allegations commonly investigated by OIA include the misuse of government computers to view pornographic material or to operate a side business, violence in the workplace, time and attendance abuse, vandalism, and misuse of government travel or purchase cards. Some of these cases may involve criminal conduct that is presented for prosecution but may be declined due to a failure to meet prosecutorial thresholds, in which case the matter is referred to FDA management to pursue administrative remedies.

FDA is the only entity in HHS, other than OIG, that has the benefit of its own unit dedicated to criminal investigations and staffed with experienced federal agents. FDA assigns a small number of these experienced agents to OIA to conduct internal investigations of alleged misconduct which, if not addressed promptly and professionally, could undermine public confidence in FDA. Although no other HHS operating division, other than OIG, uses criminal investigators to conduct internal non-criminal investigations, these other operating divisions, unlike FDA, do not have an existing staff of experienced criminal investigators.

FDA's practice is consistent with the long-standing practice of numerous other federal agencies and departments that use criminal investigators to investigate allegations of both administrative and criminal misconduct.

2. **Is there any reason to believe that non-criminal investigations of FDA employees could not be handled adequately by non law-enforcement personnel at FDA? If so, please explain.**

Prior to the establishment of OIA in 1995, FDA primarily relied on non-law enforcement personnel in its Division of Ethics and Program Integrity (DEPI) to conduct non-criminal investigations of FDA employees. In May 1993, Congressman Dingell, then-Chairman of the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, issued a report that found that DEPI was unable to conduct thorough reviews of allegations of internal wrongdoing and that OIG had limited capability to fulfill this role. Chairman Dingell recommended that FDA develop an internal capability to investigate allegations of wrongdoing through a team "with the capability of undertaking internal investigations on short notice, and trained to conduct investigations appropriately." FDA created OIA in 1995 largely due to these findings and recommendations.

3. **If it is determined to continue using FDA criminal investigators to investigate non-criminal allegations involving FDA employees, please provide the justification.**

The criminal investigators assigned to OIA are experienced agents with training in critical areas such as investigative and interviewing techniques, investigative analysis, and evidence collection. There are no non-law enforcement personnel at FDA with the same level of investigative training and experience and knowledge of FDA practices and procedures, as the federal agents assigned to OIA. Although FDA could attempt to hire or train non-law enforcement personnel to conduct internal non-criminal investigations, we believe that it would be difficult to acquire non-law enforcement personnel with the same level of investigatory skills and training and the same knowledge of FDA, as the current OIA investigators. Because FDA's current investigative system successfully addresses allegations of non-criminal misconduct with few complaints, and its use of criminal investigators is consistent with the practice of other federal agencies, FDA believes that additional training or hiring is unnecessary and would not be a sensible use of limited resources. We are concerned that transferring responsibility for internal investigations of alleged non-criminal misconduct to non-law enforcement personnel would result in less prompt and less thorough reviews of alleged misconduct.

FDA believes that its current practice of staffing OIA with experienced criminal investigators is beneficial to both FDA and the public. OIA, which is staffed with experienced, impartial agents from FDA's OCI, provides essential support to FDA and its public health mission. FDA strongly believes that all allegations of wrongdoing by FDA employees must be investigated expeditiously and objectively. Any perception that alleged misconduct is not being

investigated promptly and professionally could undermine public trust in FDA and the products that it regulates. By using its most highly trained investigators to pursue allegations of employee misconduct, FDA sends a strong signal to its staff and the public that FDA employee misconduct will not be tolerated and that allegations against its employees will be subject to the same high level of scrutiny applied to allegations against outside entities. Transferring responsibility for these important investigations to less-experienced personnel with less investigative training would signal a lack of commitment to the detection of internal misconduct and could ultimately have a detrimental impact on both employee morale and public confidence in FDA.

4. If it is determined to stop using FDA criminal investigators to investigate non-criminal allegations involving FDA employees, how would such investigations be handled?

As noted above, FDA believes that its current practice of staffing OIA with experienced criminal investigators is beneficial to both FDA and the public.

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Because of your continued interest in the role of OCI at FDA, we would like to share with you some information about FDA's recent efforts regarding OCI. In August 2009, FDA formed the OCI Center Coordination and Alignment Review Committee (the Steering Committee), composed of senior leadership from across the Agency, including OCI, the Office of Regulatory Affairs (ORA), the Office of the Commissioner (OC), and the Centers. This Steering Committee was formed to examine opportunities and develop recommendations to enhance coordination, communication, and strategic alignment between OCI and other Agency components. In addition, four associated working groups were formed and assigned specific tasks identified by the Steering Committee.

First, we recognize the need for improvement in 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 ORA can formulate effective regulatory policies and effectively allocate resources for inspections and risk communications, 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 in the process of 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, as well as making appropriate referrals to OCI.

FDA is also instituting mechanisms 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. As part of this effort, FDA will establish regularly scheduled senior level and staff level meetings between the Centers, OCI, ORA Headquarters/District Offices, and other FDA components and OCI.

Another recommendation from the Steering Committee was to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Criteria 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.

The Steering Committee also recommended 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 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, FDA now is posting initiated and completed disqualification and debarment actions online.

Finally, the Steering Committee recommended that FDA improve the coordination of its response to threats to the supply chain for FDA-regulated products, such as drugs and infant formula. Potential threats include cargo theft, 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 as 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. We have sent the same letter to Mr. Walden.

Sincerely,

Jeanne Ireland

Jeanne Ireland
Assistant Commissioner
for Legislation