DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Daniel Levinson
Inspector General
Office of the Inspector General
Department of Health and Human Services
Washington, DC 20001

September 14, 2007

Dear Mr. Levinson:

I have received your Memorandum dated September 6, 2007 notifying me of the Office of Inspector General's (OIG's) intent to withdraw from the Memorandum of Understanding (MOU). The MOU has been in effect between our organizations since 1998, and governs the procedures used by FDA and OIG to investigate allegations of misconduct by FDA employees. I welcome the opportunity to discuss this issue with you and look forward to implementing your decision in a way that is mutually beneficial to our agencies. However, before we meet to discuss next steps, I would like to put the MOU in historical perspective and to correct some of the misleading impressions your note to me may create to readers who are not familiar with the facts. Finally, I will discuss how we might proceed so that both of us continue to achieve our organizations' missions in the absence of the MOU.

As you know, a Federal Register Notice was published on January 23, 1995, formally establishing the FDA/Office of Internal Affairs (FDA/OIA). This effort was undertaken in large part after Congressman Dingell, Chairman of the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, issued a report in May 1993 recommending that "FDA develop an internal capability . . . to address allegations of wrongdoing with potentially significant programmatic effect, or allegations of improper management actions . . . ."

After obtaining OIG concurrence with the proposed formation of FDA/OIA, an organizational proposal was forwarded to the Office of the Secretary for approval. In 1998, the MOU between FDA/OIA and HHS/OIG was put into place setting forth both the procedures to be observed during investigations of FDA alleged employee misconduct and the respective roles of FDA/OIA and HHS/OIG during the conduct of such investigations.

To the best of my knowledge, FDA/OIA has worked within the letter and the spirit of the MOU during the 9 years of its life span and promptly notified HHS/OIG of every FDA employee misconduct case that developed into a criminal investigation as well as every matter that could create an actual or apparent conflict of interest. Likewise, as the MOU makes clear, it has always been HHS/OIG's statutory authority to assume responsibility for "any" investigation initiated by FDA/OIA. Finally, since the inception of the MOU, the Special Agent in Charge of FDA/OIA

has met on a monthly basis with the HHS/OIG Headquarters Officials to discuss ongoing investigations, matters of mutual concern, and areas for possible improvement.

To date, FDA/OIA has pursued nearly 1,000 criminal and administrative investigations covering a broad spectrum of alleged wrongdoing by FDA employees including, for example, theft, forgery of documents, misuse of government vehicles and computers, sexual harassment, and outright threats or problematic behavior that could result in potential workplace violence issues. All of these cases were rapidly investigated and brought to prompt resolution by FDA/OIA. Of the 1,000 criminal and administrative investigations initiated by FDA/OIA since the inception of the MOU, HHS/OIG has chosen to participate in, or lead, the investigation in a few instances. Since 2004, FDA/OIA has opened approximately 265 investigations and HHS/OIG elected to get involved in about 15 of them. In several other instances, FDA/OIA referred matters to HHS/OIG that we did not believe were appropriate for FDA/OIA to investigate because they involved either sensitive allegations (that could pose the appearance of a conflict) or a senior Agency official; however, HHS/OIG declined to accept the referrals. Currently there are two such referrals in which OIA has made several appeals to the HHS/OIG Headquarters Officials to investigate; those appeals have been denied.

One of the reasons mentioned in your memorandum prompting your intent to rescind the MOU is continuing "difficulties in consistently applying its terms, both in the exchange of information and the assignment of cases . . . ." This language may be read to suggest that FDA has not met its obligations under the MOU. This concerns me deeply because one of the stipulations in the MOU is that representatives of FDA/OIA and HHS/OIG meet on a monthly basis. Although I understand that such meetings occurred regularly and that there were many other opportunities to discuss and resolve such issues, e.g., phone calls, informal memoranda, etc., I have been advised that FDA/OIA was not informed either orally or in writing of the difficulties you reference. If you have particular examples of such difficulties, FDA/OIA and I would have welcomed hearing about them and certainly would have addressed them at the time they were raised. In the absence of such examples, I am confident that FDA/OIA has handled and continues to handle its investigations professionally, expeditiously, and within the parameters of the MOU. However, I would welcome a discussion about such difficulties now, even though the MOU is being rescinded.

We are pleased to see that HHS/OIG intends to devote increased attention and resources to alleged criminal conduct by government employees. I am confident that in the absence of the MOU, HHS/OIG will thoroughly and promptly investigate and resolve all cases of alleged criminal conduct by FDA employees and notify FDA in writing when such resolutions occur. As I am sure you can appreciate, allegations of wrongdoing by public employees are taken seriously by FDA, Congress, and the public and any perception that such matters are not being expeditiously and carefully investigated will undermine the public's trust in FDA and the industries and products that it regulates. There is an additional reason why FDA must be notified as soon as criminal matters are resolved by HHS/OIG. Often, alleged misconduct has both criminal and administrative aspects. Per current policy, administrative matters cannot be addressed by FDA until the criminal matters have been addressed. Any delayed resolution or failure to communicate resolutions of criminal matters will also impede FDA's ability to use its administrative authorities. For these reasons, to the extent practical and consistent with law

enforcement protocols, FDA must be able to account for the proper resolution of matters that are referred to HHS/OIG.

I agree that we must work together to assure that the dissolution of the MOU has the least possible adverse impact on any ongoing investigations. In order to maintain the public trust in FDA, it is essential that all employee misconduct cases involving an alleged criminal violation are promptly investigated and resolved. I believe that effective collaboration between FDA/OIA and HHS/OIG is still the best way to achieve this important goal, and I look forward to working with you to ensure a smooth transition.

Sincerely,

Andrew C von Eschenbach, MD
Commissioner of Food and Drugs