DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

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Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
U.S. Department of Health & Human Services
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Sharfstein:

This letter is sent in response to your February 23, 2010, request to Elton Malone, Special Agent in Charge (SAC), Office of Inspector General (OIG), Office of Investigations (OI), Special Investigations Branch (SIB). During your contact with SAC Malone, you requested information concerning the status of an OIG investigation into potential misconduct at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). This matter was investigated by OIG/OI/SIB. Although it is not normally the practice of OIG to release information concerning the status of internal employee-related investigations to non-complaining parties or entities, I have determined that an exception is warranted in this case as this matter has attracted significant media attention resulting in both FDA and the Department of Health & Human Services (HHS) receiving repeated external requests regarding the potential impact the allegations may have had on the safety of the American people. These factors have contributed to my decision to respond to your request with some of the relevant investigative findings of the investigation. The official status of this investigation is 'closed,' and no specific findings were referred to FDA for further action related to any FDA employee, as OIG determined none was warranted.

By way of background, the OIG investigation was predicated on allegations that CDRH management engaged in misconduct relating to the scientific review of applications for pre-market approval of radiological devices. Additionally, supplemental allegations included reprisal by CDRH management. After reviewing the complaint, OIG determined that the allegations were able to be categorized into the following:

1. CDRH management ignored scientific and legal deficiencies in approving and clearing devices;
2. CDRH management failed to follow center guidance for resolving scientific disagreements between management and scientific reviewers;
3. CDRH management did not include required documentation in the administrative files;
4. CDRH management denied branch staffers access to aspects of the administrative files;
5. CDRH management failed to comply with good guidance practices;
6. CDRH management threatened branch staffers with discipline if they did not follow direct orders to violate the law; and
7. CDRH management retaliated against several employees.

As part of the OIG investigation, investigators interviewed employees and mangers with CDRH concerning these allegations. Investigators found that many issues involved were management decisions, administrative in nature, and outside of the scope of the criminal investigation. Upon completion of a review of all relevant information, investigators found no evidence of potential violation of law, prohibited personnel practices or retaliation. Upon completion of the investigation, no presentation was made to the United States Department of Justice as the investigation failed to find any evidence of criminal activity on the part of FDA employees.

In conclusion, this matter is 'closed,' and is no longer under investigation by my office. Based on the facts gathered no prosecution is being sought, nor administrative violations referred to FDA management, as no violations were identified which were previously unknown by FDA management.

Sincerely,

Timothy J. Menke
Deputy Inspector General
for Investigations