

From: CDRH Center-Wide Agency Info Sender
Sent: Friday, November 05, 2010 10:27 AM
To: CDRH Subscribers
Subject: Office of Inspector General Investigation

I am writing to provide you with an update on an investigation by the Office of Inspector General (OIG) at the Department of Health and Human Services into management practices at CDRH.

The OIG has recently been conducting a special inquiry to assess and review allegations against CDRH management related to the approval of medical devices over the last several years. Earlier this week, the OIG informed us that this special inquiry has concluded. The inquiry found no evidence of retaliation by CDRH management against complainants and no evidence of material violation of rules with respect to documenting significant decisions, such as product approval decisions, as alleged by complainants.

This special inquiry follows a previous OIG investigation, which concluded in February 2010 and did not find evidence of potential criminal violations of law, prohibited personnel practices, or retaliation on the part of CDRH managers.

I take seriously allegations of wrongdoing by CDRH managers and staff, and I will take appropriate action if allegations prove true. For this reason, FDA leadership has provided the OIG with full access to our employees and to our records. CDRH also hired an independent contractor to investigate allegations of other problems not reviewed by the OIG, such as failures of administrative processes. I will receive a report of their findings in the coming weeks and will let you know what the contractor found.

In addition, we have taken several actions to assure that our Center has a work environment in which staff and managers can freely express their opinions. On October 1 of last year, we implemented a new standard operating procedure for resolving internal differences of opinion. In the Spring of 2010, ICF International (ICF), an Office of Personnel Management contractor, conducted an organizational assessment of the Center that included a CDRH-wide survey, focus groups, and individual interviews. ICF found that overall our strengths are employee engagement with our mission, employee trust in first-line supervisors and a solid foundation of formal dispute management processes. In their report ICF made several recommendations to enhance the workplace, such as steps to improve internal communications and training opportunities.

CDRH employees were given an opportunity to comment on those proposals over the summer. Having reviewed your feedback we are now moving forward to implement those recommendations. In doing so, we will continue to assess our programs and our work environment to look for other opportunities for improvement.

I look forward to our continuing to work together to make our Center's work environment as strong and supportive as possible.

Jeff