INVESTIGATIVE MEMORANDUM

February 4, 2010
Unknown FDA Employees
Rockville, Maryland
FDA-Internal Program / Standards of Conduct Violations
H-08-20505-3

This is the closing investigative memorandum (IM).

On December 3, 2008, HHS-OIG-SIU, received a letter from the Food and Drug Administration (FDA), Office of the Commissioner, Assistant Commissioner for Integrity and Accountability. The letter alleged managers in FDA's Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), Radiology Devices Branch (RDB) engaged in misconduct relating to the scientific review of applications for pre-market approval or clearance of radiological devices. Additionally, supplemental allegations by the scientific reviews include allegations of reprisal by CDRH management.

ALLEGATIONS

An initial review of numerous allegations followed by a series of interviews of the complainants and other staff within CDRH and RDB the allegations were solidified to the seven listed below.

1. CDRH/ODE/RDB management ignores scientific and legal deficiencies in approving and clearing devices.

2. CDRH/ODE/RDB management fails to follow center guidance for resolving scientific disagreements between management and scientific reviewers.

3. CDRH/ODE/RDB management does not include required documentation in the administrative files.

4. CDRH/ODE/RDB management denies branch staffers access to aspects of the administrative files.

5. CDRH/ODE/RDB management fails to comply with good guidance practices.

6. CDRH/ODE/RDB management has threatened branch staffers with discipline if they do not follow direct orders to violate the law.

7. CDRH/ODE/RDB management has retaliated against several branch staffers.

INVESTIGATIVE FINDINGS

Investigative efforts including interviews of members of CDRH, ODE, RDB, FDA's Office of General Counsel (OGC), and others components were conducted. Similarly, documents were reviewed and expert opinions were obtained during the investigation. The findings for each allegation are addressed below.

1. CDRH/ODE/RDB management ignores scientific and legal deficiencies in approving and clearing devices.

This allegation referred to the Premarket Approval Application (PMA's) and 510K notifications for safety and effectiveness. It was alleged that management overturned the reviewer's recommendations without having the expertise to make that decision. This allegation was in reference to a Computer Assisted Detection Device (CAD), specifically PMA #P010038/ S012 iCAD-ISI Mammo Reader. Based on the review of ODE's device evaluation procedures and interviews it was determined that no violation of the law had taken place. A procedural interpretation dispute between reviewers and its managers was the only finding that revealed during the investigation.

2. CDRH/ODE/RDB management fails to follow center guidance for resolving scientific disagreements between management and scientific reviewers.

The allegation was based on concerns that some reviewers have in where they believe that management is failing to follow procedures in accordance to ODE Blue Book Memorandum on Documentation and Resolution of Differences of Opinion on Product Evaluations (G93-1). Interviews of ODE, RDB, OGC staff, as well as an exhaustive review of documents were conducted and there was no evidence of any violations of law had taken place. Evidence of differences of opinion on the interpretation of the G93-1 was found in the interpretation. An internal review by CDRH management determined that improvements and changes needed to be made. As a result, CDRH management with the input of CDRH staff and representatives of the National Treasury Employees Union (NTEU) enhance procedures and implemented changes on the G93-1.

3. CDRH/ODE/RDB management does not include required documentation in the administrative file.

This allegation was based on the complaint from some RDB scientific reviewers that believed that management at ODE and RDB level included misleading information on the iCAD supplemental labeling of the P010038/S012 Mammo Reader device. Interviews and review of documents did not reveal evidence of a violation of law. The investigation revealed an internal disagreement between scientific reviewers and ODE and RBD managers on determining of what information should be included on the iCAD device. The ODE Director made the final decision on the labeling of the device after consultation with the scientific reviewers that made the allegation and others. A final decision was made by the ODE Director on the information of the label with the disagreement of some scientific reviewers, but without violating any laws.

4. CDRH/ODE/RDB management denies branch staffers access to aspects of the administrative file.

This allegation was a second part of allegation number 3. Some RDB scientific reviewers believed that management at ODE and RDB were denying access to the administrative files relating to iCAD, Shina Systems 510K and Hologic PMA supplement. After a review of the process management does have control of the administrative files after the RDB reviewers have submitted their consultations. Everyone involved does have access to the administrative file system; however it does restrict the ability to change or add documents once the consultations are completed. However members of the review team can make changes as part of the scientific dispute process. The investigation revealed that this allegation was based on that some reviewers were not in agreement when ODE and RDB management made decisions contrary to the reviewers recommendation, but the G-93-1 process had already taken place. The investigation did not reveal any violation of law.

5. CDRH/ODE/RDB management fails to comply with good guidance practices.

This allegation was based on the issuance of an October 7, 2008, memorandum from the ODE Director to the Radiology Premarket Review Staff referring to the process of Premarket Review of Computer Assisted Detection Devices (CAD). With this memorandum the ODE Director intended to clarify and describe the approach that reviewers should take when reviewing CAD submissions and to keep in mind that the process should be based on scientific and regulatory principles and to further be aware on following the guidelines of the G93-1 Blue Book when confronting differences of opinion on product evaluations. This guidance memorandum was interpreted by some RDB reviewers as an attempt of the ODE Director to change G93-1 guidelines and hence failing to comply with good guidance practices. The investigation revealed that there was no violation of law or good guidance practices. Interviews of ODE and RDB management revealed that the intent of the issuance of the memorandum was an attempt from ODE and RDB managers to further clarify and assist its staff on the usage of G93-1 practices to handle the growing number of difference of opinion disputes on premarket review evaluations.

6. CDRH/ODE/RDB management has threatened branch staffers with discipline if they do not follow direct orders to violate the law.

This allegation was based on complaints from some RDB reviewers that they believe that if they did not follow management instructions they would be disciplined. The investigation revealed that at no time anyone within CDRH was given any orders to violate the law. The allegation of violating the law was based on the misinterpretation by some RDB reviewers of evaluation procedural guidelines, but no evidence of exposure to violate the law ever occurred. There were some isolated incidents in where ODE and RDB management did warn some of their staff for insubordination when disagreements occurred during the premarket review process of devices. Only on one instance there was an email from an RDB manager that was directed to a few members of a review team for purposefully disrupting the process and insubordinate behavior. This was based on a disagreement of an action letter to the company Hologic on one of their devices in where the manager deemed the issuance of this letter by reviewers as inappropriate

and viewed as unacceptable performance. Specifically after the manager had made a determination that the issuance of the letter was not warranted. The issues involving this allegation are of a management nature and no evidence of potential violation of law was found.

7. CDRH/ODE/RDB management has retaliated against several branch staffers.

Allegations of retaliation were made by one ODE and several RDB staffers. All complainants were interviewed individually on several occasions and given the opportunity to provide documents and information relating to what they believed was a retaliatory action against them. For some of the complainants their sole complaint was based on the results of their Performance Management Appraisal Program (PMAP). A review of these PMAP's did indicate some numeric changes from others in the past, but none received an unacceptable rating. The PMAP's reviews did not show any indication of a retaliatory action or prohibited personnel practice. The investigation did reveal that these changes may had occurred due to the fact that the RDB Chief retired and new managers on an acting capacity at the ODE and RDB level were now rating the PMAP's, but no evidence of retaliation was found.

Other allegations were made based on the transfer of a staffer from one branch to another and the termination and changes of contracts for Medical Officers. On the issue of transferring a member of the RDB branch to another branch the investigation revealed that there is a cooperative agreement among FDA centers to share employees on a 50/50 time basis to benefit their mission and the employee. However, this agreement can be terminated at any time by the center, office or branch if they determine that the share program is not benefiting either party. In this case an office recalled their employee from the RDB due to their short staff needs and they no longer benefited from the share program. No evidence of retaliation was found.

On the issue of contract termination and changes of the number of contract years, FDA does have the authority to make these changes as a business practice and for the needs of the agency. No evidence of retaliation, prohibited personnel practices or violation of law was found.

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No evidence of prohibited personnel practices; retaliation or violations of law were discovered during the investigation. No other investigative steps are required therefore this case is closed.

Approved:
Elton Malone
Special Agent in Charge