DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 6 2007

TO: Andrew C. von Eschenbach
Commissioner
Food and Drug Administration

FROM: Daniel R. Levinson
Inspector General

SUBJECT: Memorandum of Understanding Between the Food and Drug Administration and the Office of Inspector General

A Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Office of Inspector General (OIG) setting forth the roles and responsibilities of each office concerning internal investigations involving FDA employees was negotiated in 1998. For the reasons outlined below, OIG intends to withdraw from the MOU and assume responsibility for investigations of potential criminal misconduct by FDA employees.

First, it is important that there be consistency in the manner in which OIG handles internal investigations involving all departmental employees. OIG does not have an MOU authorizing shared investigative responsibility for criminal investigations of employee misconduct with any other Operating or Staff Division. This important area of OIG investigative responsibility should be handled uniformly throughout the Department, with primary investigative responsibility resting with OIG.

The return of this function to OIG is also consistent with the Inspector General Act of 1978, as well as Federal regulations at 45 CFR §§ 73.735-1301 and 1302 and Chapter 5-10 of the Department's "General Administration Manual," which require Department employees or supervisors to report nonfrivolous allegations of "criminal offenses" (including conflicts of interest) to OIG.

To ensure integrity in the process of conducting sensitive employee misconduct investigations and based on our experience operating under the MOU, this function is more appropriately placed in an investigative office with statutory independence. OIG can more appropriately handle sensitive internal employee misconduct inquiries because OIG investigators are entirely independent of the programs and officials being investigated.

OIG has a dedicated unit of investigators assigned to handle sensitive investigations of Department officials. This Special Investigations Unit (SIU), established in 2004, will independently investigate allegations concerning senior FDA officials and thereby eliminate

any conflict of interest—in fact or appearance—created when FDA Office of Internal Affairs (OIA) agents are asked to investigate allegations of misconduct against a supervisory official.

Since entering into the MOU in 1998, there have been difficulties in consistently applying its terms, both in the exchange of information and the assignment of cases. Although improved during the past year, these problems continue.

Increased congressional and media scrutiny regarding allegations of potential criminal violations of Federal conflict-of-interest statutes and regulations involving FDA and other officials in the Department has resulted in OIG's devoting increased attention and resources to ethics issues. As a result, OIG investigators and attorneys have developed significant expertise in handling these complex cases.

OIG wishes to terminate the MOU with the least disruption possible to FDA and to ongoing cases. We would like to work collaboratively with OIA to ensure a smooth transition and to minimize any adverse impact on OIA staff. In this regard, OIG and OIA can explore the possibility of detailing personnel for a defined time period to assist in coordinating the transfer of cases.

We look forward to working with you and your staff on this important endeavor.

Attachments:
Tab A: April 10, 2007, Memorandum to the Acting Deputy Secretary
Tab B: Memorandum of Understanding - FDA/OIG

TAB A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

APR 10 2007

TO: The Acting Deputy Secretary
Through: COS _____
ES _____

FROM: Inspector General

SUBJECT: Office of Inspector General's Activities Regarding Employee Misconduct Issues – **INFORMATION**

ISSUE

To describe the Office of Inspector General's (OIG) activities within the Department regarding referral of potential criminal employee misconduct and planned actions related to referral of employee misconduct cases to OIG from the Food and Drug Administration (FDA).

DISCUSSION:

Federal regulations at 45 CFR §§ 73.735-1301 and 1302 and Chapter 5-10 of the Department of Health and Human Services' (Department) "General Administration Manual" (GAM) require employees to report nonfrivolous allegations of "criminal offenses" (including conflict of interest) to OIG. In contrast, allegations of "improper conduct" (in which no criminal activity is involved) either may be reported to OIG or may be investigated by the respective Operating Division (OPDIV).

Through reports in the press, as well as inquiries from Congress, OIG became aware that OPDIVs may not be following the CFR or the GAM and, instead, are internally evaluating potential criminal violations and not referring the matters to OIG, as required. Specific cases brought to OIG's attention included potential criminal conflict-of-interest violations.

In response to these events, and to help ensure the appropriate referral of conflict-of-interest cases from the OPDIVs to OIG, the Office of Investigations (OI) developed a referral form titled "Referral of Potential Criminal Conflict of Interest or Ethics Violations." This new form serves two functions. First, it enables OIG investigators and attorneys to quickly determine whether a potential criminal violation exists and to return noncriminal matters to the OPDIV for timely administrative followup. Second, the form assists OIG in conducting efficient investigations and ensuring that OIG has the basic documentation necessary for meaningful and expeditious consultation with the Department of Justice, as required by law. After receiving several referrals utilizing this

new form, OI determined that its use resulted in an improved referral. This form was provided to the Office of General Counsel in early 2007 for distribution and use throughout the Department.

Additionally, in an effort to address potential criminal employee misconduct issues throughout the Department, the OIG Special Investigations Unit (SIU) has increased outreach to the OPDIVs. On a monthly basis, the Director of SIU meets with representatives from FDA, Office of Criminal Investigations, Office of Internal Affairs (OIA), to discuss individual cases and referrals. Similarly, the SIU Director meets quarterly with other Department officials of the NIH Police and the Centers for Medicare & Medicaid Services (CMS) to ensure efficient identification and appropriate referrals of conflict-of-interest and related employee misconduct matters.

As part of OIG's ongoing effort to assess OPDIV referral procedures to ensure uniformity throughout the Department, OIG is undertaking a review to determine if the 1998 Memorandum of Understanding (MOU) between FDA and OIG is an appropriate vehicle for the referral of such cases. The FDA MOU is somewhat unique because in addition to the requirements of the CFR and GAM, it requires OIA to "...support the OIG's criminal investigations that involve FDA employees." OIA is also required to notify OIG if OIA determines that a criminal violation has potentially been committed by an FDA employee. Over the next 180 days, OIG will be evaluating the effectiveness and feasibility of utilizing the MOU to govern the procedures for the referral of potential criminal employee misconduct.

OIG will continue to work with all OPDIVs to address matters that involve potential criminal activities. In addition, OIG is available to meet with senior officials throughout the Department regarding the processes utilized by OPDIVs and employees to notify OIG of potential criminal matters.

Daniel R. Levinson

Daniel R. Levinson

Attachments
Tab A – "General Administrative Manual": 5-10
Tab B – Referral of Potential Criminal Conflict of Interest or Ethics Violations
Tab C – Memorandum of Understanding – FDA/OIG

SUBJECT: RESPONSIBILITY AND PROCEDURES FOR REPORTING MISCONDUCT AND CRIMINAL OFFENSES

5-10-00 PURPOSE

This chapter sets forth Department of Health and Human Services (HHS) policies, procedures, and assignments of responsibility for reporting allegations of:

A. Improper conduct not related to loyalty and security matters; and,

B. Criminal offenses against the United States.

5-10-10 DEFINITIONS

A. As used in this chapter, "improper conduct" includes the performance of one's assigned duties in a manner which contributes to abuse or waste of the taxpayers' money, which threatens the integrity of HHS programs and operations, which is contrary to the standards of conduct established by the appropriate authority, or which constitutes a prohibited personnel practice (see 5-10-50).

B. As used in this chapter, "criminal offenses" include, but are not limited to, bribery; fraud; perjury; conflict of interest; embezzlement; misuse of funds, equipment, and facilities; and other violations of criminal law by Government officers and employees, grantees, contractors, and other persons doing business with the Department. Note that some potential criminal offenses may also constitute "improper conduct" as defined above (e.g., travel voucher fraud). Such allegations should be reported in accordance with 5-10-40, entitled Procedures for Reporting Criminal Offenses.

C. As used in this chapter, "administrative offenses" are those incidents of improper conduct which can and should be handled directly by supervisors with the assistance of their servicing personnel office. A list of administrative offenses is shown in Exhibit 5-10-A.

D. This chapter does not cover procedures for the handling of matters related to loyalty and security; employee grievances; equal employment opportunity complaints, including sexual harassment complaints; classification appeals; or other matters for which a formal Governmentwide review system has been established by the Federal Government.

5-10-20 GENERAL POLICY

A. In order to provide objective uniform procedures for the handling of allegations of wrongdoing covered by this chapter, it shall be the responsibility of the Office of Inspector General (OIG) to investigate allegations of wrongdoing reported to the OIG or to refer such allegations to the appropriate operating division (OPDIV), the appropriate staff division (STAFFDIV), to Assistant Secretary for Administration and Management (ASAM), to another law enforcement agency, or to another appropriate authority.

B. Every employee, supervisor, and management official shall report any allegations of criminal offenses he/she receives, immediately to the OIG, unless it is clear to him/her that the allegation is frivolous and has no basis in fact.

C. Every employee, supervisor, and management official shall cooperate with the OIG during the conduct of any investigation.

D. Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, take or threaten to take any action against any employee as a reprisal for making a complaint or disclosing information to a supervisor, management official, or the OIG. This prohibition does not apply if the employee who made the complaint, or disclosed the information, knew the information provided was false.

5-10-30 PROCEDURES FOR REPORTING ALLEGATIONS OF IMPROPER CONDUCT

A. Submission of Allegations

Allegations of improper conduct (non-criminal) should normally be submitted in writing by an employee to his/her supervisor, a higher management official within the employee's organization, or the OIG. Allegations should, where possible, be supported by any available documentation. Oral reports are, however, acceptable, and may be necessary if immediate action is required.

B. Reporting of Allegations

Supervisors and management officials shall report any allegations of improper conduct (non-criminal) received or observed to the OIG or the next highest Department official within their organization. The head of each OPDIV or STAFFDIV is responsible for ensuring that all allegations of improper conduct, other than those that are clearly frivolous and have no basis in fact, are either investigated by the responsible component within that agency or referred to the OIG for its consideration of the appropriate action to take.

C. Investigation of Allegations

1. Allegations of improper conduct (non-criminal) received by the OIG will be reviewed promptly and a decision made as to whether an investigation is warranted. Normally, the administrative offenses shown in Exhibit 5-10-A will be handled by the employee's supervisor. If an investigation is warranted, the OIG will determine whether the investigation is to be conducted by the OIG, by an OPDIV, STAFFDIV, by ASAM or by other appropriate authority, based upon the following considerations:

   a. An OPDIV or STAFFDIV may conduct a non-criminal investigation within its own organization when the OIG determines that the OPDIV or STAFFDIV is able to conduct the investigation in a fair and impartial manner.

   b. The ASAM may conduct an investigation that the OIG determines involves prohibited personnel practices or non-criminal violations of established standards of conduct. The ASAM may also conduct investigations of cases directly referred to the Department by the Office of Special Counsel (OSC).

   c. The OIG may conduct an investigation of any allegation of misconduct received from any source.

2. Whenever the OIG determines an inquiry initiated by an OPDIV or STAFFDIV would more appropriately be handled by the OIG, the OIG may assume responsibility for completing the investigation.

D. Action on Investigation Reports

1. Where an investigation of improper conduct is conducted by an OPDIV or STAFFDIV, the head of the OPDIV or STAFFDIV will proceed as he/she determines is necessary based upon the findings of the investigation. He/she will inform, where appropriate, the Inspector General (IG), the Secretary, or other Department officials of his/her findings. Such reports will be in writing.

2. Where an investigation is conducted by the OIG, the OIG will determine if the findings of the investigation require additional action. Where appropriate, the IG will inform the head of the OPDIV or STAFFDIV, the Secretary, or other Department officials of his/her findings. Such reports will be in writing.

3. Where an investigation of improper conduct is conducted by ASAM, the Assistant Secretary will take whatever action he/she determines is necessary based upon the findings of the investigation, or will refer the findings to the appropriate authority for such action. Where appropriate, he/she will inform the IG, the Secretary, or other Department officials of his/her findings, and request further action be taken as warranted by the findings. Such reports will be in writing.

E. Record-Keeping

1. The OPDIV or STAFFDIV head, ASAM, or the IG shall ensure that a file is maintained on each investigation which is initiated. The investigation file shall contain complete documentary material showing in detail: the basis for the investigation, the extent of the investigation, persons interviewed and information furnished, records reviewed and information obtained, and any other material pertinent to the investigation. The file shall also contain a record of the action taken. Files so maintained by an OPDIV or STAFFDIV, or ASAM shall be made available to the OIG upon request.

2. Investigative files shall be retained by the office which conducted the investigation for a period of 10 years from the date of its completion.

5-10-40 PROCEDURES FOR REPORTING ALLEGATIONS OF CRIMINAL OFFENSES

A. Cooperation With the Attorney General

The Department will cooperate fully with the Attorney General (AG) and his/her staff in reporting, conducting, and assisting with investigations of alleged criminal offenses against the United States. Through the Deputy Inspector General for Investigations (DIGI), OIG, the Department will promptly report to the AG alleged violations of law by its employees and agents.

B. Authority of Office of Investigations

1. The DIGI, who heads the Office of Investigations (OI), has been designated by the Secretary and the IG, as prescribed by Appendix 3 of title 5, United States Code to:

   a. Provide liaison for the Department with the AG and his/her staff on all investigative matters; and,

   b. Conduct investigations of alleged cases of criminal wrongdoing by HHS employees, grantees, contractors, and other persons doing business with the Department.

2. The authority of OI includes authority to undertake or authorize others to undertake such investigations without the prior approval of higher officials. The authority generally does not include investigations of matters related to loyalty and security; employee grievances; equal employment opportunity complaints, including sexual harassment; employee civil rights; tort claims; and similar administrative activities that are under the jurisdiction of other HHS offices.

C. Reporting Violations of Title 18 U.S.C. (Criminal Offenses) by HHS Employees, Grantees, Contractors and Others Doing Business with the Department

1. Any HHS employee who has knowledge of possible criminal offenses against the United States by another HHS employee, grantee, contractor, or any other person doing business with the Department, shall immediately report such information directly to the OIG, to his/her supervisor or to any management official.

2. Supervisors or management officials shall immediately report any allegations or complaints of criminal offenses received, or observations of criminal conduct, directly to the OIG. The head of each OPDIV or STAFFDIV shall insure that no other action will be taken in regard to the subject of the complaint, without first consulting with OIG. The head of each OPDIV or STAFFDIV shall also insure that all such allegations which are received are referred to the OIG.

3. Allegations or complaints should normally be made in writing and include any available documentation. This method of reporting enables the OIG to make an informed decision on the handling of the alleged violation, once it is received. Oral reports, however, are acceptable if it is believed that immediate action is required by the OIG. The OI will determine if a written referral report will be required.

4. All allegations or complaints should be reported directly to the:

   Deputy Inspector General for Investigations
   Department of Health and Human Services
   Office of Inspector General
   330 Independence Avenue, S.W., Room 5409
   Washington, D.C. 20201

5. When OI has reasonable grounds to believe an HHS officer or employee has committed a criminal offense, it shall promptly notify the United States Attorney for the District in which the alleged violation occurred; the Criminal Division, Department of Justice; or the Federal Bureau of Investigation (FBI).

D. Complaints by Private Citizens

Any person desiring to bring to the attention of OIG any complaint that he/she considers warrants such attention should contact the HHS Hotline:

By Phone: 1-800-HHS-TIPS (1-800-447-8477)

By Fax: 1-800-223-8164
By E-Mail: HHSTips@oig.hhs.gov

By Mail: Department of Health and Human Services
Office of Inspector General
Hotline
P.O. Box 23489
Washington, DC 20026

E. Administrative Actions

1. Allegations Regarding Employees

a. After prosecution has been declined, or a criminal matter is otherwise closed, if administrative action by the Department appears warranted, OIG shall furnish to HHS management officials information that is relevant to their consideration of potential administrative action. Note that these referrals must be consistent with Federal classification and confidentiality laws.

b. Where OI conducts an investigation and determines that a case involves issues that are the responsibility of an OPDIV or STAFFDIV, the case shall be referred to the appropriate OPDIV or STAFFDIV for further action. The Department official who takes final action shall report the final disposition of the case to OI.

c. When a criminal investigation is ongoing and administrative action is being considered apart from the criminal investigation, the official considering the administrative action must consult with OI before implementing such action. The OI, in consultation with the Department of Justice, will assess what effect the proposed administrative action might have on the criminal investigation and advise the official accordingly. As appropriate, OIG shall furnish to HHS management officials information that is relevant to their consideration of potential administrative action. Note that these referrals must be consistent with Federal classification and confidentiality laws.

2. Allegations Regarding Non-Employees

Whenever OI informs an HHS official that it has initiated an investigation of a grantee, contractor, an employee of a grantee or contractor, or an individual doing business with the Department, the HHS official may wish to initiate administrative actions. This is a programmatic decision. Program decisions to suspend, limit, or terminate funds must be made based upon facts available, impact on the program, potential loss to the Government, and judgment as to the validity of the allegation. Officials contemplating administrative action in a case being investigated criminally will consult with OI before taking such action, to determine what effect the action may have on such investigation.

3. Investigative Reports

Reports by the FBI are the property of the FBI and are loaned to the Department. Reports by both OIG and the FBI are for official use only. Neither FBI nor OIG reports, nor their contents, may be distributed outside the component to which loaned without consultation with the FBI or OIG as appropriate. All OI and FBI reports should be stored in a secured file or safe while in the possession of the component.

F. Procedures for Requesting Investigative Assistance

Whenever the head of an OPDIV or STAFFDIV requires investigative assistance on suspected criminal activity related to his/her organization, he/she shall request the DIGI to provide such assistance. Regional officials and heads of HHS field installations shall send their requests for investigative assistance to the address listed in 5-10-40, C.4.

5-10-50 PROHIBITION OF REPRISALS AGAINST EMPLOYEES FOR PROVIDING INFORMATION

A. Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, take or threaten to take any action against any employee as a reprisal for making a complaint or providing any information pursuant to this chapter. If the complaint was made or the information was disclosed with the knowledge that it was false, or with willful disregard for its truth or falsity, any action taken against the employee based on those reasons would not constitute a reprisal action.

B. No employee shall subject another employee to harassment nor take any action against that employee as a reprisal for making a complaint or providing any information pursuant to this chapter.

C. Any employee who believes that he/she has been threatened with a personnel action or any other action, or who has been harassed or harmed by any action as a reprisal for having made a complaint or provided information pursuant to this chapter, may request the OIG to review his/her complaint about such reprisal. Whenever the OIG has reason to believe that the complaint may be true, it may, depending on the circumstances, decide to conduct the investigation or to refer the matter to OSC or ASAM for appropriate action. A more direct option an employee may exercise is filing a complaint with the OSC. The OSC has the ability to seek a stay of any agency personnel action from the Merit Systems Protection Board.

ADMINISTRATIVE OFFENSES

The improper conduct offenses listed below are considered administrative in nature. They should be handled directly by supervisors, with the assistance of members of the servicing personnel office staff. However, supervisors may also request the advice and assistance of the Office of Investigations (OI).

Improper conduct offenses which are considered administrative in nature include:

A. Leave abuse and other attendance-related offenses, such as tardiness and absence without leave.

B. Offenses related to intoxicants or other substance abuse by an individual.

C. Negligent performance of, or failure to attend to, duties.

D. Insubordinate behavior and failure to follow instructions.

E. Discourteous behavior and offensive or abusive conduct.

F. Offenses related to fighting.

G. Failure to pay legitimate debts.

H. Improper use of telephone or telephone charge card.

I. Other minor infractions of a non-recurring nature.

US Department of Health & Human Services
Office of Inspector General
Referral of Potential Criminal Conflict of Interest or Ethics Violations

REFERRING INFORMATION:

Referring Party Name:	**Referring OPDIV:**
Referring Office Name :	**Office Phone:**

EMPLOYEE/CONTRACTOR INFORMATION:

Subject Full Legal Name:		**Position/Title/Series & Grade:**
DOB:	**OPDIV/Branch/Agency:**	**Social Security Number:**

ALLEGATION INFORMATION: (Provide brief summary of each violation)

Check ☑ alleged violation(s):

☐ **Violation of Criminal Ethics Statutes**	Description: (Please cite specific statute):
☐ **Criminal Violation of Standards of Ethical Conduct**	Description: (Please cite specific standard):
☐ **Department Policy Violation**	Description (Please cite specific HHS-wide policy):
☐ **OPDIV Policy Violation**	Description (Please cite specific ODPIV policy):
☐ **Other Government Regulation**	Description (Please cite specific regulation):

US Department of Health & Human Services
Office of Inspector General
Referral of Potential Criminal Conflict of Interest or Ethics Violations

Please submit the following documents as applicable or provide a brief explanation of why they are not being submitted.

For the relevant time periods

☐	Position Description
☐	Performance Plan & Evaluation
☐	HHS 520: Request for Approval of Outside Activity
☐	SF278 / SF450: Public Financial Disclosure / Confidential Financial Disclosure report
☐	Copy of OPDIV/Branch/Agency/Institute policy governing violation(s)
☐	Copies of prepared reports/memorandums regarding interviews/meetings with the referred employee/contractor.
☐	Copies of any electronic mail messages or other correspondence relating to this matter
☐	Copy of the incoming allegation
☐	Copies of certificates or other evidence of all relevant ethics and/or conflict of interest training received by employee/contractor

Any Additional Remarks/Information:

Directions: Please complete this form and submit all of the information requested for each person you are forwarding to OIG for review. Only one (1) employee/contractor per form.

Please submit to:

Director, Special Investigations Unit
DHHS/OIG/OI/SIU
Wilbur J. Cohen Building
330 Independence Avenue, SW
Room # 5409
Washington, DC 20201

The Department's General Administrative Manual (5-10-20) requires that allegations of potential criminal conduct by HHS employees be referred to the OIG. OPDIVS may choose to refer non-criminal violations to the OIG as they deem necessary. In referring such non-criminal conflict of interest or ethics matters, this form may also be utilized.

Memorandum of Understanding

Between the Food and Drug Administration

and

Office of Inspector General

Department of Health and Human Services

PURPOSE:

Recognizing the statutory mandates of both components, and their important roles, and the necessity for maintaining a capable and trained internal investigational unit to conduct internal investigations, to provide a centralized investigative liaison between the Food and Drug Administration (FDA) and the Office of Inspector General (OIG), and to support the OIG's criminal investigations that involve FDA employees, the two components enter into this Memorandum of Understanding concerning the procedures they will observe in internal investigations involving FDA employees.

THE OFFICES

A. The Office of Inspector General

The Inspector General Act of 1978, Public Law 95-452, as amended by Public Law 100-504, 5 U.S.C. App., established the Office of Inspector General as an independent office within the Department of Health and Human Services (HHS). A major purpose of the OIG is to "conduct and supervise audits and investigations relating to the programs and operations of [HHS]." Section 2(1) of the Inspector General Act. The Act further provides that, "in carrying out the

duties and responsibilities established under this Act, each Inspector General shall report expeditiously to the Attorney General whenever the Inspector General has reasonable grounds to believe there has been a violation of Federal criminal law." Section 4(d).

B. The Office of Internal Affairs

The FDA, including its Office of Criminal Investigations (OCI), is a component of HHS and is responsible for implementing the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq. and other statutes. The Office of Internal Affairs (OIA), which is staffed by special agents detailed from OCI, was authorized and established by the Secretary of HHS, within the FDA, Office of Commissioner, to conduct internal investigations of employee misconduct. 60 Fed. Reg. 4417 (January 23, 1995). The OIA Statement of Organization states that OIA "provides a centralized investigative liaison between FDA and [OIG]" and shall serve "as an FDA investigative resource to conduct internal FDA investigations and to support OIG investigations." Id.

PROCEDURES

1. FDA will continue to ensure that its Office of Internal Affairs (OIA) is properly equipped and supported and staffed with trained and experienced criminal investigators (1811-series), and will continue to refresh the OIA staff by assigning agents from FDA's Office of Criminal Investigations to the OIA for duty tours on a rotating basis.

2. The OIG will continue to staff its FDA investigations with trained and experienced criminal investigators (1811-series) and will endeavor to provide adequate resources for investigations so as to enable OIA to investigate promptly after allegations are made.

3. OIG and FDA's OIA shall have prompt access to all files and documents within the FDA relevant to their investigations, and the resulting open investigative files and documents of these investigative entities shall be disclosed outside the Department only to prosecutors and other law enforcement entities, consistent with applicable law and regulation and as necessary to accomplish the respective missions of the OIG and OIA.

4. When OIA receives an allegation of criminal misconduct or violation of the HHS standards of conduct by an HHS employee, OIA shall immediately notify the OIG in writing or by electronic mail. Similarly, when OIG receives an allegation of criminal misconduct or violation of the HHS standards of conduct by an FDA employee it shall, as appropriate with its role under the Inspector General Act, immediately notify OIA in writing or by electronic mail. This notification by the OIG should occur unless the OIG determines that the notification is inconsistent with its role under the Inspector General Act.

5. If, at any point during an investigation, OIA determines that a criminal violation has likely been committed by an FDA employee, OIA shall immediately notify the OIG in writing or by electronic mail. If at any point during an OIG investigation, OIG determines that a criminal violation by an FDA employee has likely occurred, but the OIG determines it will not investigate that violation, it will, as appropriate with OIG's role under the Inspector General Act, immediately notify the OIA in writing or by electronic mail.

6. In recognition of the availability and performance of the FDA OIA, as an existing, trained, equipped and supported investigative unit engaged in investigations of allegations of violative or illegal conduct by FDA employees, and to avoid the duplication of resources and effort that would result from dual focus on any particular investigation, both components anticipate that such investigations will be conducted expeditiously by FDA's OIA, subject to OIG's reservation

of the right in all cases to pursue a case jointly with OIA, or, after consultation with OIA, to replace OIA as the primary agency assigned to an investigation of an FDA employee. OIA will maintain an open file until it receives a final summary and disposition from the OIG on such cases. Any referral of an investigation by the OIG to the OIA will be made expeditiously, enabling OIA to begin any necessary investigation on current information. If OIA believes that its development of an investigation requires issuance of a subpoena duces tecum, it may request that the OIG pursue the case jointly with the OIA.

7. A headquarters OIG/OI supervisor will meet with the OIA Special Agent in Charge on a monthly basis for the purpose of examining all open investigations or cases, preliminary investigations, and any other informal investigative matters which in the judgment of OIA would be of interest to OIG. OIA will provide OIG with a report of all open investigations or cases, preliminary investigations, and any other informal investigative matters which in the judgment of OIA would be of interest to OIG. The outcome of all cases and investigations concluded during the course of the previous month will also be discussed at this meeting.

8. The OIA will provide reasonable notice to the OIG prior to any presentation to the Department of Justice of an investigation in order to allow OIG to participate in the presentation if OIG chooses.

This Memorandum of Understanding is entered into voluntarily by both OIG and FDA. It may be modified at any time by agreement of the parties and may be terminated upon thirty days prior written notice by either agency.

This Memorandum of Understanding shall become effective upon the date of signing by both parties and shall continue until it is modified or terminated.

Signed this 30th day of July, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration

June Gibbs Brown
Inspector General

TAB B

Memorandum of Understanding

Between the Food and Drug Administration

and

Office of Inspector General

Department of Health and Human Services

PURPOSE:

Recognizing the statutory mandates of both components, and their important roles, and the necessity for maintaining a capable and trained internal investigational unit to conduct internal investigations, to provide a centralized investigative liaison between the Food and Drug Administration (FDA) and the Office of Inspector General (OIG), and to support the OIG's criminal investigations that involve FDA employees, the two components enter into this Memorandum of Understanding concerning the procedures they will observe in internal investigations involving FDA employees.

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duties and responsibilities established under this Act, each Inspector General shall report expeditiously to the Attorney General whenever the Inspector General has reasonable grounds to believe there has been a violation of Federal criminal law." Section 4(d).

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The FDA, including its Office of Criminal Investigations (OCI), is a component of HHS and is responsible for implementing the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq. and other statutes. The Office of Internal Affairs (OIA), which is staffed by special agents detailed from OCI, was authorized and established by the Secretary of HHS, within the FDA, Office of Commissioner, to conduct internal investigations of employee misconduct. 60 Fed. Reg. 4417 (January 23, 1995). The OIA Statement of Organization states that OIA "provides a centralized investigative liaison between FDA and [OIG]" and shall serve "as an FDA investigative resource to conduct internal FDA investigations and to support OIG investigations." Id.

PROCEDURES

1. FDA will continue to ensure that its Office of Internal Affairs (OIA) is properly equipped and supported and staffed with trained and experienced criminal investigators (1811-series), and will continue to refresh the OIA staff by assigning agents from FDA's Office of Criminal Investigations to the OIA for duty tours on a rotating basis.

2. The OIG will continue to staff its FDA investigations with trained and experienced criminal investigators (1811-series) and will endeavor to provide adequate resources for investigations so as to enable OIA to investigate promptly after allegations are made.

3. OIG and FDA's OIA shall have prompt access to all files and documents within the FDA relevant to their investigations, and the resulting open investigative files and documents of these investigative entities shall be disclosed outside the Department only to prosecutors and other law enforcement entities, consistent with applicable law and regulation and as necessary to accomplish the respective missions of the OIG and OIA.

4. When OIA receives an allegation of criminal misconduct or violation of the HHS standards of conduct by an HHS employee, OIA shall immediately notify the OIG in writing or by electronic mail. Similarly, when OIG receives an allegation of criminal misconduct or violation of the HHS standards of conduct by an FDA employee it shall, as appropriate with its role under the Inspector General Act, immediately notify OIA in writing or by electronic mail. This notification by the OIG should occur unless the OIG determines that the notification is inconsistent with its role under the Inspector General Act.

5. If, at any point during an investigation, OIA determines that a criminal violation has likely been committed by an FDA employee, OIA shall immediately notify the OIG in writing or by electronic mail. If at any point during an OIG investigation, OIG determines that a criminal violation by an FDA employee has likely occurred, but the OIG determines it will not investigate that violation, it will, as appropriate with OIG's role under the Inspector General Act, immediately notify the OIA in writing or by electronic mail.

6. In recognition of the availability and performance of the FDA OIA, as an existing, trained, equipped and supported investigative unit engaged in investigations of allegations of violative or illegal conduct by FDA employees, and to avoid the duplication of resources and effort that would result from dual focus on any particular investigation, both components anticipate that such investigations will be conducted expeditiously by FDA's OIA, subject to OIG's reservation

of the right in all cases to pursue a case jointly with OIA, or, after consultation with OIA, to replace OIA as the primary agency assigned to an investigation of an FDA employee. OIA will maintain an open file until it receives a final summary and disposition from the OIG on such cases. Any referral of an investigation by the OIG to the OIA will be made expeditiously, enabling OIA to begin any necessary investigation on current information. If OIA believes that its development of an investigation requires issuance of a subpoena duces tecum, it may request that the OIG pursue the case jointly with the OIA.

7. A headquarters OIG/OI supervisor will meet with the OIA Special Agent in Charge on a monthly basis for the purpose of examining all open investigations or cases, preliminary investigations, and any other informal investigative matters which in the judgment of OIA would be of interest to OIG. OIA will provide OIG with a report of all open investigations or cases, preliminary investigations, and any other informal investigative matters which in the judgment of OIA would be of interest to OIG. The outcome of all cases and investigations concluded during the course of the previous month will also be discussed at this meeting.

8. The OIA will provide reasonable notice to the OIG prior to any presentation to the Department of Justice of an investigation in order to allow OIG to participate in the presentation if OIG chooses.

This Memorandum of Understanding is entered into voluntarily by both OIG and FDA. It may be modified at any time by agreement of the parties and may be terminated upon thirty days prior written notice by either agency.

This Memorandum of Understanding shall become effective upon the date of signing by both parties and shall continue until it is modified or terminated.

Signed this 30th day of July, 1998

Michael A. Friedman, M.D.
Lead Deputy Commissioner
Food and Drug Administration

June Gibbs Brown
Inspector General