



United States  
**Office of Government Ethics**

1201 New York Avenue, NW., Suite 500  
Washington, DC 20005-3917

October 10, 1997

Edgar M. Swindell  
Designated Agency Ethics Official  
Department of Health and Human Services  
700-E Humphrey Building  
200 Independence Avenue, SW.  
Washington, DC 20201

Dear Mr. Swindell:

The Office of Government Ethics (OGE) has recently completed a review of the Food and Drug Administration's (FDA) ethics program. This review was conducted pursuant to section 402 of the Ethics in Government Act of 1978, as amended. Our objectives were to determine the ethics program's effectiveness and compliance with applicable laws and regulations. To achieve our objectives, we examined the following program elements as they were administered in 1996: the public and confidential financial disclosure systems, the ethics training program, ethics counseling and advice services, the coordination between ethics officials and the Office of Internal Affairs, and the acceptance of gifts of travel from non-Federal sources under 31 U.S.C. § 1353. The review was conducted intermittently from May through August 1997.

Based upon the results of our review, we have concluded that FDA's ethics program is effectively administered by dedicated and knowledgeable officials within the Division of Employee and Labor Management Relations, Ethics Branch (EB). This report highlights the results of our review.

#### PROGRAM ADMINISTRATION

Ethics officials within EB are primarily responsible for administering FDA's ethics program, working in coordination with the Department of Health and Human Services' (HHS) Office of Special Counsel for Ethics (OSCE). EB is comprised of a chief, a special assistant, and nine Program Integrity Specialists (specialists), all of whom have been delegated authority for administering FDA's ethics program and work full time on ethics. EB officials have exhibited great initiative in elements of program administration, continually striving to better this already commendable program. At all levels of this program, good communication and coordination are evident. In addition, FDA's former Commissioner showed strong support for the ethics program by being personally involved in developing policies regarding prohibited financial interests. This support, no doubt, contributed to the program's success and excellence.

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Our review of the ethics program focused on the 1996 time frame when the specialists worked on specialized areas of the ethics program. Since that time, EB has reorganized into a team-based organization in which specialists are ethics generalists, administering all elements of the ethics program for assigned centers within FDA in order to better meet the needs of FDA employees. EB maintains strict oversight over elements of the program that have been redelegated to administrative officers in field offices, and to special Government employee (SGE) programs officers who administer the day-to-day elements of the ethics program for SGEs. A noteworthy initiative is the Ethics Advisory Board (Board). The Board is scheduled to become active in October of this year and will compose internal FDA ethics policies and examine ethics issues and employees' concerns.

#### FINANCIAL DISCLOSURE SYSTEMS

We found that both the public and confidential financial disclosure systems were well administered, including the alternative confidential reporting system administered for certain SGEs. Particularly impressive were the thorough review of reports and the painstaking follow up. EB maintains considerable resources to aid reviewers in identifying potential conflicts of interest, including an extensive internal prohibited holdings listing compiled annually by a contractor for EB.

#### Public Financial Disclosure System

The public financial disclosure system at FDA is effectively administered through a cooperative effort between ethics officials at OSCE and EB. All public reports are submitted to and reviewed by EB. OSCE then further reviews and certifies those reports filed by Schedule C and certain high-level filers; EB certifies all other public reports filed by FDA employees. The reports were generally submitted and reviewed timely. The public system could, however, be strengthened by improving the timeliness of identification of new entrant filers.

To evaluate FDA's public financial disclosure system, we examined 50 of the SF 278s required to be filed in 1996, including 8 new entrant and 42 incumbent reports. Forty-five of the reports were filed timely, but two incumbent and three new entrant reports were filed late. Two of the late new entrant reports were filed in excess of 30 days past the filing deadline, thus invoking the statutorily required \$200 late filing fee. This fee must be remitted or the new entrant filers must request waivers from OGE.

FDA's office of personnel is responsible for identifying new entrant and termination filers and notifying EB to begin the filing process. According to EB ethics officials, the timeliness of this identification process varies. This process should be refined in

order to forestall late filing and the invocation of the late filing fee in the future.

All 50 public reports were reviewed in a timely manner and appeared to be reviewed thoroughly, as indicated by notations on the reports and evidence of communication with the filers. Furthermore, EB officials make themselves personally available to aid public filers throughout the filing process, further illustrating EB officials' commitment to administering an exemplary ethics program. The review process is tracked on a data base through final certification to facilitate efficient administration of the system. Our examination of the reports revealed few technical and no substantive deficiencies.

#### Confidential Financial Disclosure System

We selected for examination 151 of the confidential financial disclosure forms required to be filed by FDA employees in 1996. Two reports we requested were unavailable because the filers have failed to file, despite repeated attempts by EB officials to collect the reports. We therefore examined 149 reports, including 145 incumbent and 4 new entrant reports. Notwithstanding the two uncollected reports, we found that, in most cases, reports were filed and reviewed timely.

Twelve of the 149 reports were filed late and 5 were reviewed late. EB has adopted increasingly stringent measures to compel filers to file as required, including a standard series of reminder letters to filers, and ultimately letters to filers' supervisors. These measures have met with success, but EB continues to seek a remedy that will elicit full compliance. We endorse these efforts and encourage EB to persevere in this endeavor. As with the public system, we found that reports were reviewed thoroughly. We identified few technical and no substantive deficiencies on the reports.

#### Confidential Certification For New Employees

All new FDA employees, who were not assuming positions requiring the filing of an SF 278 or OGE Form 450, had been required to file an FDA Form 1608, "Confidential Certification of Financial Interests for New Employees." This form asked employees to indicate whether or not they (1) were in compliance with FDA's general prohibition on employees, spouses, and minor children holding financial interests in significantly regulated organizations, found in HHS' supplemental standards of conduct regulation at 5 C.F.R §§ 5501.104 and 5501.101(c)(2), or (2) required an agency determination regarding their holdings. Ethics officials reconsidered the usefulness of FDA Form 1698 and decided to discontinue its use. However, during future initial ethics

orientation sessions, new employees will be given a hand out which explains FDA's prohibited holdings policy. EB officials believe this should be a sufficient means, in lieu of the FDA Form 1608, by which to raise the awareness of new employees regarding the policy.

#### Certificates Of Divestiture

An issue concerning the way in which certificates of divestiture are processed by FDA and HHS ethics officials was raised during the course of the review. The issue is currently under review by OGE's Office of General Counsel and Legal Policy.

#### Special Government Employees

FDA employs approximately 900 SGEs. OGE has approved the use of Form FDA 3410 as an alternate confidential reporting format for most SGEs. Approximately 10 percent of FDA's SGEs continue to file the OGE Form 450 on an annual basis; the remaining 90 percent file the Form FDA 3410 prior to each meeting in which they participate.

We examined all Form FDA 3410s filed by members of two advisory committees and one advisory panel prior to specific meetings in 1996. We found that every report had been thoroughly reviewed and processed in a timely manner. In addition, the several corresponding 18 U.S.C. § 208(b)(3) waivers were processed efficiently and were accompanied by thorough documentation. FDA has developed a waiver checklist and a waiver criteria document which streamline the process.

We examined all § 208(b)(3) waivers granted in relation to the three meetings subject to our examination and found that all decisions were made in a timely manner and in accordance with applicable regulations. Each waiver underwent no less than three layers of review, and was ultimately approved or disallowed by an official in the FDA Deputy Commissioner's office, who was delegated authority to grant waivers. We were so impressed with FDA's program for protecting SGEs from conflicts of interest that we intend to point to their program as a model for other agencies to use in developing their own systems and procedures.

#### EDUCATION AND TRAINING PROGRAM

EB administers an effective ethics education and training program. Support is provided by OSCE. Initial ethics orientation is accomplished as part of a general orientation program presented twice monthly at headquarters by EB officials, and as needed in field offices by administrative officers. Initial ethics orientation consists of presentation of a film, discussion concerning financial disclosure, and the distribution of appropriate written materials. Orientation is strongly linked to the new entrant filing process for those employees who are filers.

FDA ethics officials provided a copy of their 1996 Annual Ethics Training Plan, as required. The 1996 annual training at headquarters included a film, a question and answer period hosted by a EB official, and the distribution of appropriate materials. Annual training in field locations mirrored the training provided at headquarters, except any questions that administrative officers were not able to answer were forwarded to EB officials. EB officials will conduct training in the field upon request, although the practice is becoming more limited as a result of stricter budgets.

Orientation and annual training are tracked using sign-in sheets. According to EB officials, attendance is good and annual training sessions often include employees who are not required to receive training. EB expected to begin 1997 annual ethics training in September and would again include a film and written ethics materials.

Ethics training for SGEs is provided within three main committee groups, to whom EB provides films and written materials. SGEs working individually receive training from a contact person to whom EB provides training materials. EB has already distributed the 1997 SGE ethics training materials.

#### ETHICS COUNSELING AND ADVICE SERVICES

We examined a sample of the several hundred written opinions EB issued in 1996 and 1997 on ethics matters. The examination revealed that the counseling and advice issued by EB are in compliance with applicable laws and regulations and have provided FDA employees with useful guidance in response to their questions. EB officials refer questions to OSCE when necessary.

#### ACCEPTANCE OF GIFTS OF TRAVEL

FDA has a highly sophisticated and effective system for approving the acceptance of payment for travel and related expenses from non-Federal sources pursuant to 31 U.S.C. § 1353 and the implementing regulations at 41 C.F.R. part 304-1. Officials in FDA's Office of Financial Management ensure that the acceptance of such travel by FDA employees is approved in advance and payment is made either in-kind or reimbursed by check payable to the U.S. Government. This was yet another impressive element of the FDA ethics program.

#### COORDINATION WITH THE OFFICE OF INTERNAL AFFAIRS

A working relationship exists between EB and the Office of Internal Affairs (OIA). Although the offices do not maintain constant communication, ethics issues are discussed as appropriate.

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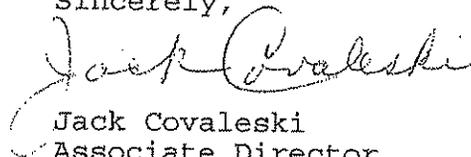
According to OIA's Special Agent in Charge, any referrals of possible violations of the criminal conflict of interest statutes are made through HHS' Office of Inspector General.

#### CONCLUSIONS

EB officials administer an excellent ethics program. The few deficiencies we found were minor. We were very impressed by ethics officials' commitment to serving FDA's employees through the efficient and responsible administration of all elements of the ethics program. We would also like to acknowledge the excellent work of the committee management officials who are involved in administering parts of the ethics program for SGEs. Their work has been critical in ensuring committee members' compliance with ethics program requirements.

In closing, I wish to thank the OSCE and EB officials, as well as all other FDA officials, who participated in this review for their cooperation and their efforts on behalf of this ethics program. A follow-up review is usually scheduled within six months from the date of our report. However, in light of your exemplary ethics program, we have no recommendations; and, therefore, this will not be necessary. A copy of this report is being forwarded to HHS' Inspector General. Please contact Laura Lanigan or Doug Chapman at 202-208-8000, if we may be of further assistance.

Sincerely,



Jack Covaleski  
Associate Director  
Office of Agency Programs

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