United States
Office of Government Ethics
1201 New York Avenue, NW., Suite 500
Washington, DC 20005-3917

August 17, 2005

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) recently completed a review of the Department of Health and Human Services' (HHS) 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 (Ethics Act). Our objective was to determine the program's compliance with applicable ethics laws and regulations. We also evaluated the system and procedures for ensuring that ethics violations do not occur. The review was conducted intermittently between November 2004 and February 2005.

HIGHLIGHTS

We found FDA's ethics program to be well served by a professional and highly organized Ethics and Integrity Staff (Ethics Office) that is dedicated to maintaining a strong ethics program for the over 9,000 employees who serve throughout FDA's six Centers and its Offices of Commissioner and Regulatory Affairs. We found the ethics program to have many strong program elements to ensure the public's confidence in an ethical Government and we commend FDA on implementing several changes to help improve and strengthen its program to ensure the integrity of its employees.

We are making two recommendations to directly enhance the effectiveness of FDA's ethics program. These improvements include: (1) ensuring FDA's confidential reports are filed by regular FDA employees in a timely manner in accordance with 5 C.F.R. § 2634.903(a) and (b) and (2) ensuring that FDA's Ethics and Integrity Administration Advisory Board establish a written policy regarding exemptions to the prohibitions on holding financial interests in significantly regulated organizations at 5 C.F.R. § 5501.104, including an interpretation of "exceptional circumstances."

Finally, as we noted during our exit conference, we identified several procedural issues at FDA which have either already been corrected or the Ethics Office has assured will be corrected in the future. Of these, most important was the immediate halt to using improper confidential financial disclosure report forms by special Government employees (SGEs) who are members of FDA's advisory committees. We are recommending that you evaluate the management of other HHS components to ensure that they are using only an OGE-approved confidential financial disclosure report form to screen SGEs for potential conflicts. In addition, we are recommending that you immediately cease reporting HHS' semiannual travel payments of more than $250 from non-Federal

sources under 31 U.S.C. § 1353 on forms other than the General Services Administration (GSA) Standard Form 326 (SF 326). Alternatively, should you decide that a form other than the SF 326 would be more beneficial to HHS' reporting needs, permission to use an alternative form must be granted by OGE in accordance with 41 C.F.R. § 304-6.4.

EMPLOYEE ETHICS SURVEY

In October 2004, just prior to our review, we conducted a survey of FDA employees to assess the effectiveness of FDA's ethics program and the agency's ethical climate from the employees' perspective. Overall, we found employee responses to our survey favorable. Most respondents indicated a familiarity with the rules of ethical conduct for executive branch employees and awareness of the officials within their agency who are responsible for addressing their ethics concerns. While ethics advice and education and training were both reported to be useful, respondents generally gave higher marks to advice than to education and training.

PROGRAM STRUCTURE

While FDA's ethics program is administered by the Associate Commissioner for Management, Office of Management within the Office of Commissioner, who serves as FDA's Deputy Ethics Counselor (DEC), the day-to-day management of FDA's ethics program is carried out by the Ethics Office which is comprised of a Director and a full-time ethics staff of approximately seven Program Integrity Advisors and Officers.[1] The Ethics Office is responsible for carrying out the majority of the ethics functions, including providing ethics advice agency-wide, implementing the requirements for both initial and annual ethics training, and managing FDA's public and confidential financial disclosure systems. However, other offices are utilized within FDA, such as the Office of Internal Affairs (OIA), the Advisory Committee Oversight and Management Staff (ACOMS), and the Office of Financial Management (OFM), to handle other aspects of the ethics program. Additionally, an attorney from your staff provides assistance to the Ethics Office as needed.

CHANGES TO HHS' SUPPLEMENTAL
STANDARDS OF CONDUCT REGULATION

Effective February 3, 2005, HHS, with our Office's concurrence, issued an interim final rule amending 5 C.F.R. part 5501 which supplements the Standards of Ethical Conduct for Employees of the Executive Branch (Standards). Among other things, amendments to the supplemental regulation address the financial interests of National Institutes of Health (NIH) and FDA employees, as well as various issues regarding outside activities. The interim final rule also amends chapter XLV of title 5 by adding new part 5502 to provide for annual supplemental reporting of outside activities and

[1] At the time of our on-site field work, the Ethics Office was seeking to hire another full-time Program Integrity Officer due to an increase in workload. In addition, to further assist the Ethics Office, we were advised that detailees are used to help with the administration of the confidential disclosure system.

supplemental reporting of prohibited financial interests. Since the conclusion of our fieldwork, HHS submitted to OGE a draft final rule which is currently under review.

OUTSIDE ACTIVITY SYSTEM

In 2004, in light of concerns about HHS employees failing to request approval for, or receiving inappropriate approvals of, outside activities, the Acting Commissioner of FDA directed that all current outside activity approvals for FDA employees be reviewed. This review covered more than 1,800 outside activity approvals for both paid and unpaid work performed by FDA employees outside of their official duties. No additional approved outside activities of concern other than the activities of one CBER employee were found.[2] Nevertheless, the Acting Commissioner authorized certain changes to help ensure the integrity of FDA employees by improving and strengthening FDA's outside activity process. These changes included: (1) requiring the Director of each product-based FDA Center to personally review all requests for outside activities; (2) eliminating the practice of approving outside activities for up to five years (prior to issuance of the amended change to the supplemental regulation); (3) developing an automated process for the submission of all outside activity requests by replacing the current HHS-520 form, Request for Approval of Outside Activity, with a new electronic version of the form (HHS-520-1) designed for FDA use only; (4) conducting annual reviews of approvals of these requests and linking them to the review of the financial disclosure reports; (5) developing an agencywide "Staff Manual Guide" on outside activities to ensure uniform practices; and (6) expanding the number of FDA employees required to file confidential financial disclosure reports (see subsection below on the Confidential System for Regular Employees).

As part of implementing these new changes, we were advised that all FDA employees, with the exception of public filers, were required to use the new HHS-520-1 form to obtain re-approval of previously approved outside activities by November 15, 2004 and to obtain approval of any prospective outside activities.[3] Also, at the time of our on-site review, we were advised that FDA's

---

[2] We were advised that an FDA Center for Biologics Evaluation and Research (CBER) employee (a confidential filer) requested approval of an outside activity to provide consulting services to a private industry company. The request was approved in October 2002 by the Director, Division of Management Services, and CBER. As part of the approval process, CBER reviewed available information on the company to determine whether FDA "significantly regulated" the company's activities under §§ 5501.101(c)(2) and 5501.106(c)(3), and concluded that they were not "significantly regulated." During a subsequent review in 2004 by CBER of its outside activity approvals, CBER reexamined the approval of this outside activity. The Ethics Office consulted with HHS and subsequently determined that the concerned company did participate in activities that were significantly regulated by FDA; therefore, outside activities with the company were prohibited for public and confidential filers. The CBER employee was advised to end all activity with the company and the employee agreed to sever the relationship, and subsequently resigned from FDA.

[3] Since the new HHS-520-1 form was not ready during the 2004 public disclosure filing cycle,
Footnote continued on the next page

"Staff Manual Guide" was in draft form and would be updated to incorporate the new changes in the supplemental regulation.

Our Current Review

Our review of FDA's outside activity prior approval system focused primarily on whether the approval requirement in HHS' supplemental regulation, at 5 C.F.R §§ 5501.101(c)(2) and 5501.106(c)(3), was being met. Our examination of the outside employment/activities reported on a sample of public and confidential financial disclosure reports (see section below on Financial Disclosure Systems) revealed that 10 outside employment/activities required prior approval; we found the appropriate HHS-520 or HHS-520-1 forms on file, none of which raised concerns about being approved inappropriately.

Additionally, we examined 71 other approved outside employment/activity approvals for both filers and non-filers who used the new HHS-520-1 from the period of November 2004 through January 2005. Although we found none which raised concerns about being approved inappropriately, the great majority of these requests were approved after the start date of the activity. After discussing this with the Director of the Ethics Office, we were advised that some confusion existed among those who were currently participating in an outside activity previously approved on the HHS-520 form but who were now required to obtain re-approval using the new HHS-520-1 form. We were also made aware of technical problems with accessing and/or completing the new HHS-520-1 through the FDA Administrative Portal[4] which the Ethics Office was working to resolve at the time of our review. Despite the confusion and technical problems, we are still pleased to see FDA taking proactive steps to strengthen its outside activity process. We believe once the new requirements in HHS's supplemental regulation are incorporated, FDA's current outside activity system will be strengthened even further.

ACCEPTANCE OF AWARDS

In addition to evaluating FDA's procedures for ensuring that outside activities were approved in accordance with HHS' supplemental regulation, we also evaluated FDA's procedures for approving the acceptance by employees of bona fide awards given for meritorious public service or achievement in accordance with 5 C.F.R. § 2635.204(d)(1). In doing so, we paid particular attention to any award that required providing a lecture or presentation to determine whether it was a bona fide award or, instead, compensation for teaching and speaking governed by the outside activities restrictions at § 2635.807.

---

public filers initially were allowed to use the HHS-520 form for approvals and re-approvals.

[4] The FDA Administrative Portal is an electronic portal that provides FDA employees access to various FDA administrative web-delivered applications.

In accordance with 5 C.F.R. § 2635.204(d)(1) and FDA guidance, employees who wish to request approval to receive awards valued at more than $200 and awards of cash or investment interests offered as awards are required to do so using the Form for Review/Approval of Awards. The employee must submit the completed form, along with any supporting documentation, to the Ethics Office for processing; however, a final determination is made by the DEC. To evaluate compliance with the requirements of § 2635.204(d)(1), we examined all four of the awards approved in 2003 and 2004. Based on our examination of each form and the accompanying documentation, all four awards appeared to have been accepted in accordance with § 2635.204(d)(1) and FDA guidance.

ENFORCEMENT

In accordance with 5 C.F.R. § 2638.203(b)(12), the Ethics Office utilizes the services of OIA when appropriate, including the referral of matters to and acceptance of matters from OIA. OIA serves as a centralized investigative liaison between FDA and HHS' Office of the Inspector General and conducts internal investigations relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by FDA employees. OIA is a component of the Office of Criminal Investigation Headquarters Staff located within FDA's Office of Regulatory Affairs and is staffed by special agents detailed from the Office of Criminal Investigation.

During our discussion with both the Director of the Ethics Office and OIA's Special Agent In Charge regarding FDA's system of enforcement, we learned that neither knew of the requirement to concurrently notify OGE when referring a case involving an alleged violation of a criminal conflict-of-interest statute to the Department of Justice (Justice). We learned that at the beginning of fiscal year 2005, OIA referred a case for an alleged violation of 18 U.S.C. § 207; however, both Justice's Office of Public Integrity and the United States Attorney's Office for the District of Maryland declined prosecution. We were also advised, at the time of our discussion, of three other working cases at OIA that were also pending referral.[5] We discussed with both officials the requirements of 5 C.F.R. § 2638.603 and were advised that in the future OIA will be responsible for notifying OGE of all criminal conflict of interest referrals and other required follow-up information. We commend the Special Agent In Charge for taking swift action in this matter by his immediate instruction to his investigative staff on the required use of OGE Form 202, Notification of Conflict of Interest Referral, when notifying OGE of all future referrals. As a result of our discussions and the fact that we received assurance that OGE will be notified of referrals in the future, we have no formal recommendation for this program area. However, as a good management practice, we encourage the Director and the Special Agent In Charge to periodically update and clarify the roles of each of their respective offices in FDA's system of enforcement.

Additionally, at the beginning of our review, we were advised that 10 administrative actions in 2004 were taken, considered, or were still pending against FDA employees for violations of the

[5] One case is from fiscal year 2004 and involves a potential § 207 violation. The other two cases are from fiscal year 2005 and involve potential § 208 violations.

Standards or statutes governing conduct. We understood at the time of our exit conference that only one action was still pending.

FINANCIAL DISCLOSURE SYSTEM

FDA's public and confidential disclosure systems are centrally managed by the Ethics Office and generally accord with statutory and regulatory requirements. Although we found many aspects of both financial disclosure systems to be sound, we identified several procedural issues within each system which have already been corrected or the Ethics Office has assured will be corrected in the future.

The one recommendation for improvement deals with the timely collection of confidential reports filed by regular FDA employees. Although we found that the Ethics Office uses a number of measures to compel filers to file as required, including a standard series of reminder letters to filers, and ultimately letters to filers' supervisors, we encourage, as we did in our October 1997 report of our last review of FDA's ethics program, that the Ethics Office continue to seek a remedy that will elicit full compliance. We will be happy to work with you to develop more effective means of ensuring timely filing.

Confidential Financial Disclosure System

FDA uses various confidential financial disclosure reports for different categories of employees. Regular FDA employees and certain SGEs file the standard confidential financial disclosure form (OGE Form 450), while other SGEs file an OGE-approved substitute disclosure form in lieu of the OGE Form 450 prior to serving on an advisory committee addressing product-specific issues.[6]

Confidential System for SGEs

FDA's ACOMS works closely with all FDA Centers to ensure consistency in the implementation of Federal Advisory Committee Act policies and HHS/FDA policies and guidelines. Currently, there are 30 standing FDA advisory committees (25 non-statutory and 5 statutory); in addition, FDA administers one HHS committee. Each advisory committee is assigned an executive secretary who is responsible for the overall administrative management of the committee.

The ACOMS Director explained the process for determining the eligibility of outside experts to participate in advisory committee meetings. In addition to the requirements of 18 U.S.C. § 208,

---

[6] The Form FDA 3410, Confidential Financial Disclosure Report For Special Government Employees, was approved in 1994 by OGE as an alternative reporting procedure for SGEs who serve on advisory committees at FDA.

FDA also implements § 505(n)(4) of the FDA Modernization Act of 1997 (FDAMA).[7] Both statutes provide for waivers of conflicts of interest under certain conditions and for public disclosure of any waiver that has been granted.

In the past, FDA struck a balance concerning how much information to disclose in any given case by disclosing the names of individual SGEs who had received waivers and identifying whether the waiver was granted under 18 U.S.C. § 208 or § 505(n)(4) of FDAMA, without disclosing any details about the actual financial interest at stake. However, in 2002, in an effort to increase transparency and establish uniformity for § 208 or § 505(n)(4) waivers, FDA established draft guidance whereby information relating to the nature and magnitude of the conflict of interest waived for an SGE's participation on a product-specific advisory committee is read into the public record, by the SGE in the form of a declaration, prior to the start of the advisory committee meeting.[8]

---

[7] FDAMA, enacted Nov. 21, 1997, amended the Federal Food, Drug, and Cosmetic Act relating to the regulation of food, drugs, devices, and biological products. FDAMA created new administrative conflict of interest and associated waiver considerations applicable to SGE members working on advisory committees under FDA's CBER and Center for Drug Evaluation and Research (CDER). Absent a § 505(n)(4) waiver under FDAMA, a CBER and/or CDER advisory committee member who provides expert scientific advice and recommendations to FDA regarding a clinical investigation of a drug or the approval for marketing of a drug may not vote on any matter if the member or the member's immediate family could gain financially from the committee's recommendations. Although FDA may grant a § 505(n)(4) waiver if the member's participation is necessary to afford the committee essential expertise, no waiver is given if the member's own scientific work is involved.

[8] While 18 U.S.C. § 208 provides for disclosure of waiver information upon request and permits agencies to redact any information that would be exempt under the Freedom of Information Act at 5 U.S.C. § 552, section 505(n)(4) of FDAMA requires SGEs to publicly disclose all conflicts of interest. To satisfy the disclosure requirements of § 505(n)(4), FDA obtained an opinion from Justice's Office of Legal Counsel which concluded that FDA has the discretion to require SGEs to disclose information sufficient to adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make. The Office of Legal Counsel also concluded that FDA could exercise its discretion in making this disclosure to avoid making the disclosure requirement so intrusive or onerous as to make SGEs unwilling to serve on advisory committees.

Additionally, to help assess what information could be disclosed pursuant to these statutes, FDA sent a survey to all advisory committee members to determine whether they would support disclosure of specific details concerning specific conflicts of interest. Based on the results of the survey, FDA concluded that no foreseeable harm would result from disclosing both the nature and dollar range of any financial interest that gave rise to a conflict for which a waiver was granted.

To help with making determinations of whether certain financial interests pose a conflict, FDA developed a document entitled Guidance for FDA Advisory Committee Members and Other Special Government Employees on Conflict of Interest 2000 (Waiver Criteria Document) to provide guidance to FDA staff, advisory committee members, and other SGEs about the policies and procedures for handling conflicts of interest with FDA advisory committee members, consultants, and experts. We found the Waiver Criteria Document to be a useful resource and were advised that it is continuously updated to reflect FDA's current thinking on the criteria for waiving conflicts of interest issues related to SGEs. Additionally, we found the table entitled Conflict of Interest Criteria Guidance to be helpful in providing clear and easy-to-use guidance for reviewers by describing the most common course of action based on FDA's experience to date.

Our Current Review

We were advised that all advisory committee members are designated as SGEs or representatives upon selection. To help screeners evaluate potential conflicts of interest relative to the concerns associated with the issues, products, and manufacturers at a product-specific meeting, SGEs are required to complete FDA Form 3410 before each meeting or task. We were advised that although this reporting format is used for approximately 90 percent of the SGEs who serve on FDA advisory committees, the remaining 10 percent complete the OGE Form 450 when serving on committees that handle more general matters or when an abundance of issues discussed would make use of FDA Form 3410 impractical.

To evaluate this alternative reporting procedure, we examined two advisory committee meetings held in 2004 for each of FDA's three largest Centers. Each of these Centers received delegated authority to review and approve both FDA Form 3410s and OGE Form 450s and to prepare all 18 U.S.C. § 208(b)(3) waivers for approval through the Ethics Office prior to an SGE's participation in a meeting or task.[9] We also examined two meetings held in the same year for a smaller committee within the Office of Commissioner, which relies on the Ethics Office to assist it in screening for potential conflicts, approving each form, and preparing waivers. For each of these meetings, we examined the committee's charter, meeting notes, § 208(b)(3) waivers, FDA Form 3410s, and OGE Form 450s filed by the attending members. We found the FDA Form 3410s submitted by attending members within the three largest Centers were filed, reviewed, and certified prior to each meeting. However, our examination of the OGE Form 450s filed by attending members at both Office of Commissioner meetings and at two meetings held within two of the three FDA Centers revealed several improper reporting issues, described below.

[9] We were advised that the three largest Centers have been delegated authority because they are active in the number of advisory committee meetings held each year and are equipped with staff members whose primary responsibility is screening for conflicts of interest and preparing waivers for Center SGEs.

First, in preparation for an upcoming committee meeting held by one Center committee, attending members filed an unauthorized verification certificate, in lieu of a new OGE Form 450, to certify that their review of their most recently filed OGE Form 450 indicated either no information change or that specified items had been added or deleted. Although the use of an alternative disclosure form for SGEs who serve terms of more than one year on advisory committees was approved for NIH's continued use in October 1996 and again in November 1997 for use by other components of HHS, we did not approve its use at FDA.[10] Additionally, the certificate lacked a reference to the Privacy Act as shown on the OGE Form 450, and the statement "I certify that the statement I have made on this form and all attached statements are true, complete, and correct to the best of my knowledge" in the signature block of the certification. Both were on the verification certificate we originally approved for use by NIH in August 1995.

Second, a variation of the certificate described above was also used in 2004 by members of the committees within the Office of Commissioner. Our examination of this certificate found that it required filers to update information after they reexamined their OGE Form 450 and, if applicable, any waiver they received. The certificate used by these committee members appeared to be a modification of the certificate approved for SAMHSA's use and was not an authorized form for FDA to use. Furthermore, this certificate also lacked the aforementioned reference to the Privacy Act and the certification statement in the signature block.

We discussed the unauthorized use of these verification certificates with the Director, who immediately responded by meeting with FDA's Advisory Committee Council[11] to discuss the matter. The use of the certificates subsequently was stopped. The Director also immediately had the Ethics Office arrange an upcoming ethics training session for Centers on the confidential disclosure system for their SGEs. We were advised that this mini-ethics training course would consist of topics such as: (1) how to determine whether the matter under consideration at an advisory committee meeting is considered a "particular matter"; (2) how to determine which form must be completed by the SGE; (3) how to review the form for conflicts of interest; (4) the 60-day review time frame and where to

---

[10] In August 1995, pursuant to 5 C.F.R. § 2634.905(c), OGE approved on a trial basis HHS' request to use a verification certificate in lieu of filing a new OGE Form 450 each year for SGEs on advisory committees at NIH. Based on OGE's year-long requirement that HHS monitor and access its experience with the certificate, the certificate was approved for continued use by NIH in October 1996. In November 1997, we approved its use at the following five additional components of HHS: Agency for Health Care Policy and Research, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration (SAMHSA). For SAMHSA we approved a modified version of the certificate, which offered more specificity and reminded filers of any existing waivers and recusals but did not alter the basic concept.

[11] The Advisory Committee Council provides for intra-agency policy consistency and for communication between ACOMS and the Centers' advisory committees' staff. The Director serves as a member of this Council.

sign to show the initial review has been conducted; (5) when an 18 U.S.C. § 208(b)(3) waiver must be prepared; and (6) various record-keeping rules. The Director also advised us that the Ethics Office would now provide more oversight to the confidential disclosure process, particularly at the smaller Centers.

As a result of these initiatives and the assurances provided by the Director in this regard, we are not making a formal recommendation to FDA for improvement in this area. However, we are recommending, pursuant to 5 C.F.R. § 2634.905(c), that you evaluate the management of other HHS-components who utilize the services of Federal advisory committees to ensure that they are using only an OGE-approved confidential financial disclosure report form to screen SGEs for potential conflicts. Should you decide that it would be beneficial for FDA to use an alternative certificate in lieu of their advisory committee members filing an OGE Form 450, you must request OGE's approval to do so.

Third, during our review it was brought to our attention that not all SGEs who file OGE Form 450s, are filing follow-on new entrant confidential disclosure reports each year as required by 5 C.F.R. § 2634.903 (b)(1). Through our discussions we learned that some FDA Center committees have pools of SGEs, appointed to terms for up to four years, who may not participate in meetings in years following the year of their appointment. In these cases, the committee management officials were not requiring a follow-on new entrant OGE Form 450 subsequent to the report that was initially filed.

We advised the Director that not only should members be designated as SGEs at the time of their appointment to the pool of SGEs, but they should also be designated annually after their term. In such cases, an annual filing is not merely a procedural requirement. Rather, it will ensure that the FDA has up-to-date financial disclosure information to consider when it selects an SGE to serve on one its panels. When initially designating SGEs at the time of their appointment, FDA would have made a good faith estimate that an individual is not expected to serve more than 130 days in the next 365-day period; such an estimate, where appropriate, should be made at the time of each designation in subsequent years.

To resolve this matter, the Director advised us that each Center will now follow the deadline of October 31, established by 5 C.F.R. § 2634.903, for collecting annually follow-on new entrant OGE Form 450s from all SGEs, including those who may not participate in a committee meeting during the calendar year. For the latter SGEs, we were advised that their reports will be submitted and initially reviewed by their Center representative, while final review and certification will be provided by the Ethics Office.

Waiver System

As previously mentioned, during our review of FDA's advisory committee meetings we examined the corresponding 18 U.S.C. § 208(b)(3) waivers granted to advisory committee members in relation to these meetings. We also selected and examined a sample of 50 waivers from over

200 § 208(b)(1) and (3) waivers issued in 2003 by FDA that were forwarded to OGE for retention. Each waiver examined appeared to comply with the requirements of 5 C.F.R. part 2640.

We are aware that the United States House of Representatives recently passed its version of the Department of Agriculture, Rural Development, FDA, and Related Agencies Appropriations Bill for FY 2006, which included a provision that would prohibit FDA from granting conflict of interest waivers to any voting member of an advisory committee or panel regardless of whether the waiver was granted under the terms of 18 U.S.C. § 208 (b)(3) or § 505(n)(4) of FDAMA. We also understand that a similar amendment may be offered during the Senate's consideration of its version of the bill.

Although it is unclear at this time what impact this may have for FDA in its handling of advisory committee members, consultants, and experts, we are closely monitoring these developments. In the meantime, we recommend that you reevaluate the criteria you have established for determining when a waiver is appropriate. The guidance may need to be revised to address concerns about FDA's standards for issuing waivers.

Confidential System for Regular Employees

As previously mentioned, in June 2004, FDA approved a major change to its filing status designations by expanding the number of employees required to file a confidential report. Previously, only non-administrative employees at the GS-14/equivalent and the Commissioned Corps (CC)-05 levels and above were required to file. However, all non-administrative positions at the GS-13/equivalent and CC-04 levels are now required to file. Additionally, employees with procurement warrants greater than $25,000; other employees identified at the discretion of Center Directors and/or senior management; specified positions, at various grade levels, throughout the Office of Regulatory Affairs; and all attorneys within the Office of the Commissioner are also required to file. With this change, FDA gained an additional 1,051 employees subject to the confidential disclosure requirements. We note that due to the timing of our review, we were unable to assess what impact the increase of new filers will have on the resources of the Ethics Office or on the compliance-based aspects of the program. Nonetheless, we encourage FDA to constantly reevaluate the resources of its Ethics Office to ensure that it receives and/or maintains the proper assistance needed to effectively administer the confidential system.

We reviewed the master lists of confidential filers and examined a sample of 200 of the approximately 5,641 new entrant and annual confidential reports required to be filed in 2003. Our sample consisted of 50 new entrant and 84 annual OGE Form 450s and 66 OGE Optional Form 450-As. We note that of the 50 new entrant reports we examined, 17 were filed late. We also identified 17 annual reports that were filed late from our examination of the 150 combined annual and 450-A reports. As I am sure you will agree, late filing diminishes an agency's ability to provide timely and specific conflict of interest advice, which is a fundamental purpose of any ethics program. Accordingly, we are recommending that you ensure confidential reports are filed by regular FDA employees in a timely manner in accordance with 5 C.F.R. § 2634.903 (a) and (b). Aside from advising filers and supervisors that appropriate administrative action can be taken against an

individual in accordance with 5 C.F.R.§ 2634.704(d) for filing late or failing to file reports, you should develop additional strategies for ensuring compliance. We would be happy to work with you in this endeavor.

Notwithstanding the late filing of reports, however, all reports were reviewed within the required 60 days and certified soon after review. We found these reports to have been reviewed thoroughly, as evidenced by the limited number of technical reporting omissions and painstaking follow-up provided, and found no substantive deficiencies.

Public Financial Disclosure System

We examined 7 of the 8 public reports required to be filed in 2004 by high-level non-Presidential appointees, for which your staff has the responsibility of providing the final review and certification. These included reports from the Acting Commissioner, the former DEC, a Schedule C appointee, and 5 career and non-career Senior Executive Service employees. Of the reports we examined, 1 was a new entrant and 6 were annual reports. Our review disclosed that all were filed and reviewed in a timely manner. However, at the time of our examination, three reports had not been certified due to additional information being sought from these filers. We later confirmed during the course of our review that the additional information had been received and the reports were certified.

To evaluate the public system for all other employees, we examined 79 of the 80 public reports required to be filed in 2004 with the Ethics Office. Of the reports we examined, there were 6 new entrant, 72 annual, and 1 termination report. The one unexamined report was another termination report which at the time of our review had not been filed. We were advised that, after unsuccessful attempts were made by the Ethics Office to obtain this report, the case was sent to your office on November 19, 2004 for further action. Finally, the filer submitted the report on January 19, 2005, absent the late filing fee. We were advised that, in accordance with HHS' late filing fee procedures, a request had been made to the debt collection office to initiate collection action.

Overall, we found the examined reports to have been thoroughly reviewed as evidenced by the annotations listed on the reports as well as on the FDA-developed, Review and Approval Worksheet, which we found to be an excellent means to record continual communication between the reviewer and filer. We also found the FDA listing of U.S. Industries (more commonly referred to as the "Yellow Book") a great resource tool for FDA employees and reviewers in helping to identify holdings as being either acceptable or prohibited by FDA. Although we found few technical and no substantive deficiencies, there were 21 annual reports that initially appeared to us to have been filed and/or reviewed late. After discussing this with the Director, we confirmed that all of the filers were provided with either a filing extension and/or the reports were provided with a timely initial review. The Director advised us that when completed public reports are submitted to the Ethics Office they are date stamped and then distributed to the appropriate Program Integrity Advisors/Officers (reviewers), who are responsible for conducting an initial compliance review. Upon their completion, the reports are forwarded to the Director, who provides a follow-up review for both

technical and conflict-of-interest compliance. If no problems are found, reports are signed by the Director and then forwarded to the DEC for final review and signature. As a result of this process, for each report we questioned, the reviewer either granted the filer an extension for filing or had to wait for additional information before forwarding the report to the Director. Although we were advised that in many instances the notes and dates of the reviewer's last communication with the filer are often included within the filer's report folder, at the time of our examination we had no access to those folders. Therefore, we suggested to the Director that reviewers should enter records of all filing extensions and other communication on the report itself in the block marked, "Comments of Reviewing Officials." In addition, we also suggested that the Review and Approval Worksheet be amended to record the same information. The Director agreed to implement both of our suggestions.

Equal Classification Determinations
for Certain Positions

On April 25, 2003, OGE issued a determination that 30 FDA positions were of "equal classification" to positions whose incumbents were required to file public financial disclosure reports, pursuant to 5 U.S.C. app. § 101(f)(3) and 5 C.F.R. § 2634.202(c). Currently, there is ongoing communication concerning your second request for an "equal classification" determination for 53 additional positions at FDA that are classified as confidential reporting positions.

Ethics and Integrity Administrative
Advisory Board

As you are aware, some FDA employees have raised concerns about § 5501.104 of HHS' supplemental regulation, which generally prohibits covered FDA employees from having a financial interest in a significantly regulated organization. The regulation contains a number of exceptions to the general prohibition, including a waiver provision that permits the FDA Commissioner (or the Commissioner's designee) to grant an individual exception to the prohibition in cases involving "exceptional circumstances." As you may recall, in response to a letter we received from an FDA employee expressing concerns about this prohibition, we wrote to you on September 19, 2001 addressing these concerns along with our findings from a review of various documents related to how the general prohibition is carried out and exceptions are granted. We were advised that in 1999, FDA established the Ethics and Integrity Administration Advisory Board (EIAAB) to provide a senior management level review of all specific and/or policy matters relating to conflicts of interest and integrity arising within FDA as well as cases of exceptions under § 5501.104, for the purpose of making recommendations to the Commissioner, through the DEC, whose decisions on all such matters become final. Although at the time of our September letter, EIABB had not been in existence long enough to develop a "track record" with regard to the granting of individual exceptions, you intended to encourage the EIABB to establish a formal FDA-wide policy regarding such requests, including an interpretation of "exceptional circumstances." Our current review found no formal policy in place. Accordingly, we recommend that this be done. We believe a formal policy regarding the exceptions would be extremely useful since the application of the general prohibition in individual cases may not be intuitive to covered employees.

Our examination of 13 cases EIAAB examined in 2003 and 2004 involving "exceptional circumstances" found that all requests for exceptions were disapproved. Based on our review of EIAAB's database, we found that in all 13 cases that the filer sold the disapproved prohibited interest within 90 days. In one other case the filer sold the interests prior to the board meeting. During the course of our fieldwork we were advised that 11 other cases were pending an upcoming review by EIAAB.

ACCEPTANCE OF TRAVEL PAYMENTS
FROM NON-FEDERAL SOURCES

Officials within FDA's OFM are responsible for ensuring that the acceptance of travel payments from non-Federal sources for travel, subsistence, and related expenses incurred by employees on official travel under the authority of GSA's regulation at 41 C.F.R. chapter 304, implementing 31 U.S.C. § 1353, are approved in advance and payment is made either in cash or in kind. OFM is also responsible for drafting the semiannual report and forwarding it through HHS to OGE.

In FDA's two most recent semiannual reports covering October 1, 2003 - March 30, 2004 and April 1, 2004 - September 30, 2004, there were 380 and 372 payments, respectively. We examined all of the 25 payments reported over $5,000, and a sample of 10 other payments of varying amounts that were listed on both reports. Although we found all of these latter 10 payments to have been accepted in accordance with 31 U.S.C. § 1353 and 41 C.F.R. Chapter 304, our examination found two issues that we discussed with the Director and an OFM official.

First, our examination of the 25 payments over $5,000 found that only 5 were accepted pursuant to § 1353, while the remainder were accepted under HHS' gift acceptance authority found at 42 U.S.C. § 3506. That authority is used for travel when employees are performing "advisory services" rather than for attending meetings or conferences. Although employees who seek approval under § 1353 are required to use the HHS-348 form, The Request for Approval to Accept Payment of Travel Expenses from a Non-Federal Source, we were advised that this form is also used to approve gift acceptances under § 3506 and 5 U.S.C. § 7342. While many of the 25 HHS-348 forms we examined did not indicate the travel authority under which the reported payments of more than $5,000 were accepted, we confirmed that this has since been corrected on a new electronic version of the HHS-348 form developed by OFM. Nevertheless, we advised both the Director and the OFM official that FDA must cease reporting payments under § 3506 for inclusion in future semiannual reports of §1353 travel payments to OGE. As we discussed at our exit conference with FDA, although we are not providing a formal recommendation in this area, we strongly suggest that as an additional safeguard, the Ethics Office begin to periodically examine FDA's semiannual reports to ensure that payments are not incorrectly accepted and/or reported to OGE under any authority other than §1353.

Second, we noted that HHS submitted FDA's own reporting form to OGE as its semiannual report of travel payments. Effective June 16, 2003, the General Services Administration published its final rule requiring the use of the SF 326 when reporting travel payments to OGE. Thus, we

recommend that you cease using any form other than the SF 326 when reporting travel payments to OGE. Alternatively, should you decide that a form other than the SF 326 would better support HHS' reporting requirements, permission to use an alternative form must be granted by OGE in accordance with 41 C.F.R. § 304-6.4.

Finally, HHS' April 1, 2004 - September 30, 2004 semiannual report to OGE had not been received by the time of our exit conference. We remind you that HHS must make every effort to send these semiannual reports in a timely and complete manner, as OGE must retain these reports for public inspection.

EDUCATION AND TRAINING

We found that FDA's initial ethics orientation program exceeds the minimal training requirements found at subpart G of 5 C.F.R. part 2638, as evidenced by the Ethics Office's commitment to provide live initial ethics orientation briefings to new employees. We attended one of these briefings and found it was linked to the new entrant filing process for those entering into a covered position. During the briefing, new confidential filers were identified and provided with an overview of the filing requirements as well as a reporting form for completion. Additionally, we were impressed to learn of the Ethics Office's efforts to conduct one-on-one initial orientation briefings with new public filers.

Although in previous years FDA complied with meeting the presentation requirements for providing annual verbal training to its public filers in accordance with 5 C.F.R. § 2638.704(c), the requirement was not met in 2004. Instead, annual ethics training for all covered employees consisted of the review of written materials, absent a written determination pursuant to § 2638.704(e) that verbal training would be impractical. After discussing the circumstances surrounding this with the Director, we are confident that in the future FDA will continue to meet this requirement as it has done so in the past. Additionally, we found the ethics coverage on FDA's Web site to be a useful resource for providing immediate access to both OGE's regulations and HHS' supplemental regulation, general guidance on areas governing ethics in Government, ethics advisories on common ethics topics, frequently asked questions, requirements of annual ethics training, and points-of-contact information for all FDA ethics officials.

Initial Ethics Orientation and
Annual Ethics Training for SGEs

Initial ethics orientation for new SGEs is accomplished as part of a day long advisory committee new member training program. As part of this training, the Ethics Office is responsible for providing a presentation which includes an overview on the most significant conflict-of-interest laws and ethics regulations that are applicable to SGEs. At the time of our examination, the most recent new member training was held on April 20, 2004. For annual ethics training, you are responsible for determining the training content for all SGEs throughout HHS. In 2003 and 2004, written ethics training in lieu of in-person verbal training, in accordance with 5 C.F.R. § 2638.705(d)(2), was provided to all FDA SGEs and consisted of a review of the

October 2004 HHS-revised memo, Ethics Rules for Advisory Committee Members and Other Individuals Appointed as Special Government Employees. Although optional for 2004, you also suggested that in addition to providing written material, SGEs could also be shown the OGE-produced videotape, The Ethical Choice: Ethics for Special Government Employees, and/or be directed to a computer-based training program to complete an ethics training module.

ADVICE AND COUNSELING SERVICES

We examined approximately 57 pieces of advice dispensed by both the Ethics Office and the attorney assigned from your staff, covering approximately 12 months. Overall, the advice appeared to be consistent with the appropriate laws and regulations and was generally rendered promptly to the questions that were posed. We did question several pieces of advice, and our questions were resolved at our exit conference.

RECOMMENDATIONS

We recommend that you take the following actions:

1. Evaluate the management of those components that utilize the services of Federal advisory committees to ensure that they are using only an OGE-approved confidential financial disclosure report form to screen SGEs for potential conflicts. Also, should you decide that it would be beneficial for FDA to use an alternative certificate in lieu of advisory committee members filing an OGE Form 450, you must request OGE's approval to do so.

2. Cease reporting HHS' semiannual travel payments of more than $250 from non-Federal sources under 31 U.S.C. § 1353 on forms other than the General Services Administration's Standard Form 326 (SF 326). Alternatively, should you decide that a form other than the SF 326 would be desirable, permission to use an alternative form must be granted by OGE in accordance with 41 C.F.R. § 304-6.4.

3. Ensure that confidential reports are filed by regular FDA employees in a timely manner in accordance with 5 C.F.R. § 2634.903 (a) and (b).

4. Ensure that FDA's Ethics and Integrity Administration Advisory Board establish a written policy regarding exemptions to the prohibition on holding financial interests in significantly regulated organizations at 5 C.F.R. § 5501.104, including an interpretation of "exceptional circumstances."

In closing, I wish to thank you and the Ethics Office for your efforts on behalf of the ethics program. Please advise me within 60 days of the specific actions HHS has taken or plans to take on our recommendations. A brief follow-up review will be scheduled within six months from the date of this report. In view of the corrective action authority vested with the Director of OGE under subsection 402(b)(9) of the Ethics Act, as implemented in subpart D of 5 C.F.R. part 2638, it is important that HHS take timely actions to implement our recommendations.

Copies of this report are being sent via transmittal letter to FDA's Commissioner and OIA's Special Agent In Charge. Please contact David A. Meyers at 202-482-9263, if we can be of further assistance.

Sincerely,

Marilyn L. Glynn
General Counsel

Report number 05-