SMG 3118.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

PERSONNEL

CONFLICT OF INTEREST

SUPPLEMENTARY PROCEDURES FOR PROTECTION AGAINST CONFLICTS OF INTEREST

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1. PURPOSE

This Guide defines the responsibilities for implementing policies set forth in FDA's Supplement to the DHHS Standards of Conduct regulations. The FDA policies prescribe additional rules and regulations for FDA employees in the following general areas:

A. Participation of new employees in certain work assignments involving regulated industry (Subpart B)

B. Outside employment/activities (Subpart D)

C. Financial interests (Subpart E)

2. APPLICABILITY

This Guide applies to all regular FDA employees, PHS Commissioned Corps personnel assigned to FDA programs, and to assignees under the Intergovernmental Personnel Act of 1970. However, it does not apply to individuals employed as "special Government employees" (e.g., advisory committee members, consultants, and experts). These employees are subject to special provisions set forth in Subpart J of the DHHS Standards of Conduct which are covered in FDA Staff Manual Guide 3118.2.

3. REFERENCES

A. DHHS Standards of Conduct (dated 1/23/81).

B. Executive Order 11222

C. FDA Supplement to the DHHS Standards of Conduct regulations (Federal Register Notice dated 2/24/78).

D. FPM Chapter 735, "Employee Responsibilities and Conduct;" DHHS Personnel Manual 735; DHHS Personnel Instruction 735-1, "Standards of Ethical Conduct."

E. FDA Staff Manual Guide 3118.3, "Supplementary Procedures Regarding Standards of Conduct - Outside Activities."

F. FDA Staff Manual Guide 1430.2,"Authority to Approve Outside Activities."

4. FORMS SUBMITTED BY EMPLOYEES

A. HHS-473, "Confidential Statement of Employment and Financial Interests."

B. FD-1608, "Confidential Certification of Financial Interests".

C. HHS-520, "Request for Approval of Outside Activity."

5. RESPONSIBILITIES UNDER SUPPLEMENTAL REGULATION

A. All employees are responsible for:

1. Being familiar with and observing the rules set forth in the DHHS Standards of Conduct and FDA's Supplement thereto.

2. Submitting a completed Form HHS-520 for advance approval of outside employment/activities in accordance with 73a.735-401, "Outside Employment - General Provisions."

3. On an annual basis, reporting all financial interests and outside activities as required.

4. Providing the Conflict of Interest Staff with data, as necessary, to evaluate the employee's financial interests to ensure compliance with the provisions of FDA's rules concerning financial interests with regulated industries, and other information necessary for finalizing the review of the report.

5. Seeking counsel from supervisor or ethics official when there is any doubt or confusion concerning the provisions contained in the DHHS Standards of Conduct, FDA Supplement, or this Guide.

B. Supervisors are responsible for:

1. Submitting employee reports and forms prompt y as prescribed in Subparts B, D, and E of Attachment A and enforcing the policies and procedures included in this Guide.

2. Reviewing Forms HHS--520 and recommending approval or disapproval to the ('enter/Office reviewing official in accordance with the DHHS Standards of Conduct and the FDA Supplement.

3. Submitting recommendations on whether or not a new position should be included in the "control activity" classification as defined in 73a.735-502(b)(1).

4. Monitoring employees with exceptions to retain financial interests to assure that they are not involved in projects which may conflict with their financial interests as stated in 73a.735-502(a).

5. Prohibiting "control activity" employees from participating in work assignments as designated in 73a.735-201(a) and (b).

6. Providing advice and guidance to employees to ensure compliance with the policies outlined in the DHHS Standards of Conduct and the Fl)A Supplement.

C. Center/Office Directors are responsible for:

1. Submitting updates as required as to who constitutes a "control activity" employee under the criteria stated in 73a.735-502(a)(1). (Field organizations reporting to ORA should forward updates through the Regional Office for review and consolidation.).

2. Ensuring that employees complete appropriate statements of financial interests and requests for outside activities, as required.

3. Approving Form HHS-520, as authorized by FDA Staff Manual Guide 1430.2.

D. Division of Ethics and Program Integrity, Conflict of Interest Staff (COI) is responsible for:

1. Researching and providing recommendations on conflict of interest questions to ensure full compliance with the FDA's ethics program, in an attempt to avoid situations which may result in apparent or actual conflicts of interests.

2. Reviewing HHS-520s submitted by employees or management officials to ensure that the requirements for outside activities have been met.

3. Monitoring receipt of forms and reports as required under the DHHS Standards of Conduct, FDA Supplement, and this Guide.

4. Ensuring compliance of the reporting requirements of the financial interest system.

5. Providing consultation and interpretative opinions to employees, supervisors, management officials, and other interested parties concerning the rules and regulations contained in the DHHS Standards of Conduct, FDA Supplement, and this Guide.

6. Maintaining confidential files on all completed forms, reports, records, and related documents. (Availability of the information from these files is prohibited except to carry out the procedures defined in Parts 73 and 73a of the DHHS Standards of Conduct regulations.)

7. Designing and instituting training programs for FDA employees on the DHHS Standards of Conduct and all related rules and regulations.