

Department of Health and Human Services

§ 73a.735-101

basis of conduct that does not adversely affect the performance of the employee or applicant or the performance of others (except criminal conviction in determining suitability or fitness).

k. Take or fail to take any personnel action when the taking of or failure to take such action violates any law, rule, or regulation implementing, or directly concerning the merit system principles (as set forth in 5 U.S.C. 2301).

[53 FR 4410, Feb. 16, 1988]

APPENDIX B TO PART 73—CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

I. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

II. Uphold the Constitution, laws, and regulations of the United States and all governments therein and never be a party to their evasion.

III. Give a full day's labor for a full day's pay, giving earnest effort and best thought to the performance of duties.

IV. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

V. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or herself or family members, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of governmental duties.

VI. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

VII. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of governmental duties.

VIII. Never use any information gained confidentially in the performance of governmental duties as a means of making private profit.

IX. Expose corruption wherever discovered.

X. Uphold these principles, ever conscious that public office is a public trust.

[53 FR 4410, Feb. 16, 1988]

PART 73a—STANDARDS OF CONDUCT: FOOD AND DRUG ADMINISTRATION SUPPLEMENT

Subpart A—General Provisions

- Sec.
- 73a.735-101 Principles and purpose.
- 73a.735-103 Responsibilities.
- 73a.735-104 Advice and guidance.

Subpart B—Miscellaneous Provisions

73a.735-201 Control activity employees formerly associated with organizations subject to FDA regulation.

Subpart C [Reserved]

Subpart D—Outside Employment

73a.735-401 General provisions.

Subpart E—Financial Interests

73a.735-501 General provisions.

73a.735-502 Employees in regulatory activities.

73a.735-504 Exceptions.

Subparts F—I [Reserved]

Subpart J—Statements of Employment and Financial Interests

73a.735-1004 Submission and review of statements.

AUTHORITY: 45 CFR 73.735-105.

SOURCE: 43 FR 7619, Feb. 24, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 73a.735-101 Principles and purpose.

(a) To assure that the business of the Food and Drug Administration (FDA) is conducted effectively, objectively, and without improper influence or appearance thereof, all employees must be persons of integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any hint of conflicting interests. This supplement recognizes FDA's public obligation to set reasonable and fair safeguards for the prevention of employee conflicts of interest. It is necessary to meet FDA's regulatory responsibilities and to otherwise assure full protection of the public confidence in the integrity of its employees.

(b) Since FDA is a unique consumer protection and regulatory agency within the Department, the DHHS Standards of Conduct need further supplementation to reflect this role.

§ 73a.735–103

Therefore, for purposes of implementing the DHHS Standards of Conduct regulations within the FDA, this supplement provides interpretive definitions and additional requirements. As further guidance to its employees and supervisory officials, FDA will issue internal procedural instructions in accordance with this supplement.

§ 73a.735–103 Responsibilities.

(a) A “control activity” employee shall be personally responsible for assuring that he does not hold an interest in any organization whose FDA-regulated activities constitute more than an insignificant part of its business as defined in § 73a.735–502(b)(2). The Associate Commissioner for Administration (or his designee) is available to assist such employees in obtaining corporate data necessary to make such a determination.

(b) Other employees are similarly responsible for observing the financial interest retention requirements in §§ 73a.735–501(b) and 73a.735–502(a)(2).

§ 73a.735–104 Advice and guidance.

(a) The Associate Commissioner for Administration (or his designee) shall provide day-to-day guidance and assistance to employees and supervisors on matters covered by regulations in Part 73 and this part of this chapter.

(b) The FDA Conflict of Interest Review Board shall review and make recommendations to the Commissioner on requests for exceptions to conflict of interest policies and procedures in regulations in this part and Part 73 of this chapter.

Subpart B—Miscellaneous Provisions

§ 73a.735–201 Control activity employees formerly associated with organizations subject to FDA regulation.

(a) For a period of 1 year after FDA appointment, or appointment to the Food and Drug Division, Office of the General Counsel, a control activity employee who was employed in a regulated organization within 1 year before FDA employment shall not participate in any regulatory action before FDA that involves the former employer organization. Exceptions may be author-

45 CFR Subtitle A (10–1–00 Edition)

ized only under paragraph (e) of this section.

(b) A control activity employee who was previously employed in a regulated organization shall not participate in any regulatory action before FDA in which the employee had participated personally and substantially in behalf of the former employer organization, e.g., drug investigations/applications, food additive petitions, matters dealing with compliance in areas of radiation-producing products or medical devices. Exceptions may be authorized only under paragraph (e) of this section.

(c) Employment in a regulated organization includes contractual relationships, e.g., attorneys who may have represented an FDA-regulated firm or industry or an association of such firms and individuals who may have served a firm, industry or association in a consultant capacity.

(d) Within 30 days after assignment to a control activity position, an employee shall submit to his supervisor detailed information concerning former industry employers, and dates and substance of involvement in such regulatory matters as may be subject to the prohibition in paragraph (b) of this action.

(e) The Commissioner may grant individual exceptions to paragraphs (a) and (b) of this section whenever he determines that strict application would not be in the best interests of the United States. A memorandum of any exception granted shall be filed for public inspection in the Public Records and Documents Center, Food and Drug Administration, Room 4–68, 5600 Fishers Lane, Rockville, Md. 20857, within 10 days after the Commissioner’s decision. The memorandum shall include the employee’s name, title, grade, summary of official duties, prior pertinent industry involvement, a brief description of the specific regulatory action in which the employee has been permitted to participate, and a statement explaining why such strict application of the subpart would not be in the best interests of the United States.

Subpart C [Reserved]