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.



## Subpart B—Miscellaneous Provisions



## Subpart C [Reserved]

## Subpart D—Outside Employment



## Subpart E—Financial Interests



## Subparts F–I [Reserved]

## Subpart J—Statements of Employment and Financial Interests



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. 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 authorized 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]

## Subpart D—Outside Employment

### § 73a.735–401 General provisions.

(a) Employees of the Food and Drug Administration shall obtain advance approval for all outside employment, whether paid or unpaid. Employment, as used in this section, does not include:

(1) Memberships in charitable, religious, social, fraternal, recreational, public service, civic, or similar nonbusiness organizations.

(2) Memberships in professional organizations. (Officeholding, however, requires advance approval.)

(3) Performance of duties in the Armed Forces Reserve or National Guard.

(b) Control activity employees (defined in § 73a.735–502) will not generally be granted approval to:

(1) Manage or direct an organization whose activities are subject to FDA regulation, or

(2) Be employed in an organization whose business activities are subject to FDA regulation unless:

(i) The regulated activities of the organization are an insignificant part of its total operations, i.e., the regulated products of the organization constitute no more than 10 percent of its annual gross sales, and

(ii) The outside employment is in nonregulated activities of the organization.

(c) All other employees will generally be granted approval to engage in outside employment which is compatible with the full performance of their FDA duties and responsibilities and which will not give rise to a real or apparent conflict of interest. Permissible employment includes but is not limited to:

(1) Employment where the sale of FDA-regulated products is incidential to the purpose of the establishment, e.g., hotels, theaters, bowling alleys, and sports arenas.

(2) Sales and clerical occupations relating to regulated products, e.g., supermarkets, drugstores, department stores, liquor stores.

(3) Trade, industrial, and service occupations relating to regulated products, e.g., gasoline service station attendant, line production or assembly work, cook, waiter, waitress, hospital attendant, snack bar vendor, warehouseman.

(d) All employees will generally be granted approval to engage in paid or unpaid outside employment which contributes to their technical or professional development, e.g.,

(1) Medical, dental, and veterinary practices.

(2) Pharmacy practice after meeting the following conditions which will serve to protect against possible conflicts or apparent conflicts of interest and to avoid other problems resulting in embarrassment to the employee or FDA:

(i) The primary purpose of the part-time employment is to contribute to the overall professional development of the employee and generally enhance his capability to better perform his current FDA duties.

(ii) The part-time duties will be confined generally to dispensing Rx drugs and related professional pharmacy duties.

(iii) The employee will avoid unrelated nonprofessional duties such as supervision or management of store operations, contractual or purchasing responsibilities (except normal ''out-of-stock'' requisitioning) and repacking and relabeling of bulk items.

(iv) The employee will demonstrate a high degree of discretion and judgment in his contacts with customers and representatives of regulated industry and competitor firms so as to avoid giving the impression that:

(*a*) His part-time actions, recommendations, opinions, or remarks are official points of view;

(*b*) He is using his FDA position for private gain by oral misrepresentations and false claims of the company's products;

(*c*) He is making a Government decision outside official channels, e.g., to customers, prescribing physicians, buyers, distributors;

(*d*) He or other FDA representatives will give preferential treatment to any regulated organization or representatives of such organizations, or that FDA employees have not exercised complete independence or impartiality in carrying out their regulatory and consumer protection responsibilities; or

(*e*) His part-time work is creating an adverse effect on the image of FDA or discrediting the integrity of official FDA regulatory decisions.

## Subpart E—Financial Interests

### § 73a.735–501 General provisions.

(a) No restrictions are placed on ownership of diversified mutual funds.

(b) An FDA employee, other than a control activity employee (defined in § 73a.735–502), may have financial interests:

(1) In an organization whose FDA-regulated activities are an insignificant part of its total operations, i.e., no more than 10 percent of the organization's annual gross sales are in products regulated by FDA; or

(2) In an organization whose FDA-regulated business activities are a significant part of its total business operations: *Provided*, That:

(i) The holding is less than $5,000 (value or cost at time of initial reporting),

(ii) The holding represents less than 1 percent of the total outstanding stock shares of that organization, and

(iii) No more than 50 percent of the employee's total investment value is concentrated in organizations whose FDA-regulated business activities are a significant part of their business operations.

(c) Notwithstanding the provisions of this part permitting employees to hold financial interests in organizations subject to FDA regulation, an employee holding such an interest shall not participate in an official matter whose outcome would have a direct and predictable effect on his financial interest. However, this prohibition is not applicable to:

(1) Diversified mutual funds, which are exempted from 18 U.S.C. 208 by § 73.735–501(a) of this chapter.

(2) Financial interests for which the Commissioner has in advance granted a written exception on the ground that the public interest would be served if a particular employee is allowed to participate in an official matter whose outcome may have a direct and predictable effect on the employee's financial interest. Such exemptions will be granted only in exceptional circumstances. Any determination to authorize such exceptions shall be made in accordance with 18 U.S.C. 208(b)(1) and documented for public inspection in accordance with § 73a.735–504.

### § 73a.735–502 Employees in regulatory activities.

(a) An employee in regulatory activities (''control activity'' employee) may hold financial interests in an FDA-regulated organization only if either of the following conditions are met:

(1) The regulated activities of the organization are an ''insignificant'' part of its total business operations, or

(2) Written approval for an individual exception is granted by the Commissioner in accordance with § 73a.735–504; however, such approval will not be considered unless all of the following conditions are met:

(i) Retention of the financial interest does not give rise to an actual conflict of interest;

(ii) Acquisition of the financial interest occurred by marriage or inheritance, or the interest was held prior to an FDA reorganization, change in regulations, or similar circumstances beyond the control of the employee that resulted in the interest becoming prohibited;

(iii) No direct relationship exists between the employee's official duties and the regulated activities of the organization in which the financial interest is held;

(iv) The employee occupies a position below that of Bureau/Deputy Bureau Director (or Assistant/Deputy General Counsel, Food and Drug Division, Office of the General Counsel); and

(v) The employee agrees to refrain from engaging, either directly or indirectly, in transactions that are designed to increase the value of his ''excepted'' financial interest.

(b) To administer provisions within this part, the following interpretations apply:

(1) A ''control activity'' employee (''control activity'' positions are identified in appendix C to part 73 of this chapter), means one who:

(i) Occupies an FDA position classified at GS–11 or above, or PHS Commissioned Officer 0–3 or above, or equivalent;

(ii) Occupies an FDA position below GS–11 with duties of a nature that the employee could in the discharge of his official duties and responsibilities cause an economic advantage for or impose a handicap on a non-Federal enterprise (includes investigators, inspectors, regulatory analysts);

(iii) Occupies a position at GS–11 or above in the Office of the Assistant General Counsel, Food and Drug Division.

(2) ''Insignificant'' (part of an organization's total business operations) means that the FDA-regulated products constitute no more than 10 percent of the organization's annual gross sales.

**§ 73a.735–504 Exceptions.**

(a) A control activity employee who can satisfy all of the conditions specified in § 73a.735–502(a)(2) may submit a request to retain a prohibited financial interest. Any such request must be submitted no later than 30 days after the event that results in the employee holding the prohibited financial interest. Such requests for exception should be forwarded in writing through supervisory channels to the Associate Commissioner for Administration for review by the FDA Conflict of Interest Review Board and subsequent recommendation to the Commissioner. All decisions on requests for exceptions shall be in writing and a copy furnished to the employee involved.

(b) A memorandum of each approved exception shall be filed in the Public Records and Documents Center for public inspection. Such public disclosure shall be made within 10 days after the Commissioner's decision. The following is an example of the format of such memorandum (in a hypothetical employee situation):

(1) Employee: Joe Doe.

(2) Title: Research Chemist.

(3) Grade/Salary: GS–14.

(4) Organization: Bureau of Biologics, Food and Drug Administration, Bethesda, Md.

(5) Date of employee's request for exception: _____.

(6) Date of Commissioner's approval: _____.

(7) Basis for exception: Employee owns financial interest in the ABC Foods Corporation, and permanent retention is normally prohibited under FDA/HHS conflict of interest regulations for such an employee. The employee, however, acquired this financial interest prior to his reassignment to FDA on _____, which was part of a major Department reorganization transferring certain functions from NIH to the FDA (i.e., FDA's Bureau of Biologics). At the time of acquisition and immediately prior to the reorganization, the employee's financial interest was allowable under Department regulations. The employee's official duties are fully confined to the matters under the jurisdiction of the Bureau of Biologics, and his official duties do not involve any contact with the food industry. The Commissioner has determined that an exception is warranted under the following criteria:

(i) Acquisition occurred prior to Department reorganization;

(ii) Financial interest retention will not give rise to an actual conflict of interest situation;

(iii) There is no direct relationship between the employee's official duties and the regulated activities of ABC Foods;

(iv) The employee occupies a position below that of Bureau or Deputy Bureau Director (or equivalent position in the Office of the Commissioner); and

(v) The employee agrees to refrain from engaging in any direct or indirect transactions that are designed to increase the value/shares of the ''excepted'' ABC Foods interests.

This exception is considered equitable to the employee involved, and retention of the ABC Foods interest will not in any way impair the interests of the Government or of the public.

(c) In interpreting the requirement of § 73a.735–502(a)(2)(v), events not involving employee discretion (e.g., accepting dividends in the form of cash or additional shares) do not constitute transactions designed to increase the value/shares of an ''excepted'' financial interest. A transaction involving discretion, e.g., exercise of stock options, may be made only if proposed to the Associate Commissioner for Administration and approved by the Conflict of Interest Review Board as an amendment to the original exception. A memorandum recording such approval shall be made public in accordance with paragraph (b) of this section.

(d) An employee may temporarily retain a prohibited financial interest pending review of a written request for an exception submitted in accordance with this section.

(e) Except as provided in § 73a.735–501(c), no employee may participate in an official matter whose outcome will have a direct and predictable effect on

a financial interest held by him. This prohibition applies to official matters handled before and after approval of an exception under this section.

## Subparts F–I [Reserved]

## Subpart J—Statements of Employment and Financial Interests

### § 73a.735–1004 Submission and review of statements.

(a) Employees occupying control activity positions shall file Form HHS–473 ''Confidential Statement of Employment and Financial Interests'' with the Associate Commissioner for Administration within 30 days after entrance in this category and annually thereafter as of June 30, or such other dates as the Secretary, with the concurrence of the Civil Service Commission, may approve. Prior to the due date, the Associate Commissioner for Administration shall advise ''control activity'' employees of the annual filing requirement through normal administrative channels. The annual reporting requirement shall commence as of June 30, 1977.

(b) The Associate Commissioner for Administration (or his designee) shall serve as the principal reviewing official for Outside Activity Forms, HHS–520 and 521, and shall make final determinations on matters arising from activities reported on Form HHS–473.

# PART 73b—DEBARMENT OR SUSPENSION OF FORMER EMPLOYEES

Sec.


AUTHORITY: 18 U.S.C. 207(j).

SOURCE: 47 FR 17505, Apr. 23, 1982, unless otherwise noted.

### § 73b.1 Scope.

This part contains rules governing debarment or disqualification action against a former officer or employee of the Department, including former and retired officers of the commissioned corps of the Public Health Service, because of violation of the post-employment restrictions of the conflict of interest laws and regulations.

### § 73b.2 Rules and regulations.

This part will be applied in conformance with the standards established by the Office of Government Ethics in its regulations, 5 CFR part 737, and interpretations thereof. Former officers and employees of the Department may request advice and assistance in compliance with those regulations from the Assistant General Counsel, Business and Administrative Law Division, Department of Health and Human Services.

### § 73b.3 Reports of violations.

(a) If an officer or employee of the Department has reason to believe that a former officer or employee of the Department has violated any provision of 18 U.S.C. 207 (a), (b) or (c) or if any such officer or employee receives information to that effect, he/she shall promptly make a written report thereof which shall be forwarded to the Inspector General. If any other person has information of such violations, he/she may make a report thereof to the Inspector General or to any officer or employee of the Department.

(b) The Inspector General shall coordinate proceedings under this part with the Department of Justice in cases where it appears criminal prosecution is warranted.

### § 73b.4 Proceedings.

(a) Upon a determination by the Assistant General Counsel, Business and Administrative Law Division, or his/her designee, after investigation by the Inspector General, that there is reasonable cause to believe that a former officer or employee, including a former special Government employee, of the Department of Health and Human Services (former departmental employee) has violated 18 US.C. 207 (a), (b) or (c), the Assistant General Counsel, or his/her designee, shall cause a copy of written charges of the violation(s) to be served upon such individual, either personally or by registered mail. The