

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 "accepted" 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: _____.

§ 73a.735-1004

(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

45 CFR Subtitle A (10-1-03 Edition)

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.