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: _____.