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