

**§ 73a.735-501**

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:

**45 CFR Subtitle A (10-1-06 Edition)**

(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: