

§ 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.