AUTHORITY: 45 CFR 73.735–105.

SOURCE: 43 FR 7619, Feb. 24, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 73a.735–101 Principles and purpose.

(a) To assure that the business of the Food and Drug Administration (FDA) is conducted effectively, objectively, and without improper influence or appearance thereof, all employees must be persons of integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any hint of conflicting interests. This supplement recognizes FDA's public obligation to set reasonable and fair safeguards for the prevention of employee conflicts of interest. It is necessary to meet FDA's regulatory responsibilities and to otherwise assure full protection of the public confidence in the integrity of its employees.

(b) Since FDA is a unique consumer protection and regulatory agency within the Department, the DHHS Standards of Conduct need further supplementation to reflect this role. Therefore, for purposes of implementing the DHHS Standards of Conduct regulations within the FDA, this supplement provides interpretive definitions and additional requirements. As further guidance to its employees and supervisory officials, FDA will issue internal procedural instructions in accordance with this supplement.

§ 73a.735–103 Responsibilities.

(a) A ''control activity'' employee shall be personally responsible for assuring that he does not hold an interest in any organization whose FDA-regulated activities constitute more than an insignificant part of its business as defined in § 73a.735–502(b)(2). The Associate Commissioner for Administration (or his designee) is available to assist such employees in obtaining corporate data necessary to make such a determination.

(b) Other employees are similarly responsible for observing the financial interest retention requirements in §§ 73a.735–501(b) and 73a.735–502(a)(2).

§ 73a.735–104 Advice and guidance.

(a) The Associate Commissioner for Administration (or his designee) shall provide day-to-day guidance and assistance to employees and supervisors on matters covered by regulations in Part 73 and this part of this chapter.

(b) The FDA Conflict of Interest Review Board shall review and make recommendations to the Commissioner on requests for exceptions to conflict of interest policies and procedures in regulations in this part and Part 73 of this chapter.

Subpart B—Miscellaneous Provisions

§ 73a.735–201 Control activity employees formerly associated with organizations subject to FDA regulation.

(a) For a period of 1 year after FDA appointment, or appointment to the Food and Drug Division, Office of the General Counsel, a control activity employee who was employed in a regulated organization within 1 year before FDA employment shall not participate in any regulatory action before FDA