

Food and Drug Administration, HHS

§5.11

procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

(36) The Secretary has delegated to the Commissioner, the authority to administer and make decisions regarding the invention and patent program as they pertain to the functions of the Food and Drug Administration and to make determinations of rights in inventions and patents in which the Department has an interest. This delegation excludes the authority to submit reports to Congress and further, it excludes those authorities under the Stevenson-Wylder Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation (under §5.10(a)(26)). All authorities other than the authority under 35 U.S.C. section 203 (March-In Rights) may be redelegated.

(37) Functions vested in the Secretary under title III, Section 354, of the PHS Act (42 U.S.C. 262 *et seq.*), as amended. The authority pertains to the Food and Drug Administration's oversight of mammography facilities.

(38) The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration, or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(39) The Secretary of Health and Human Services has redelegated to the Commissioner, of Food and Drugs, under 45 CFR 5b.8 regulations, appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regula-

tions (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(b) The Chief Counsel of the Food and Drug Administration has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335), section 4 of the Federal Import Milk Act (21 U.S.C. 144), and section 9(b) of the Federal Caustic Poison Act.

§5.11 Reservation of authority.

(a) Notwithstanding provisions of §5.10 or any previous delegations of authority to the contrary, the Secretary of Health and Human Services (Secretary) reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.