

§ 19.21

(c) All general policy relating to conflicts of interest shall be established in guidance documents pursuant to the provisions of §10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Freedom of Information Staff, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of §20.63 of this chapter.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 55 FR 1404, Jan. 16, 1990; 65 FR 56479, Sept. 19, 2000]

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Office of Internal Affairs, Office of the Commissioner, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR parts 73 or 73a or of any statute listed in appendix A to 45 CFR part 73 should report such information directly to the Office of Internal Affairs. Any such reports shall be in writing or shall with the assist-

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ance of the Office of Internal Affairs, be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Office of Internal Affairs, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985; 60 FR 47478, Sept. 13, 1995]

Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term *official responsibility* means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a

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specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

Subpart A—Official Testimony and Information

Sec.

- 20.1 Testimony by Food and Drug Administration employees.
- 20.2 Production of records by Food and Drug Administration employees.
- 20.3 Certification and authentication of Food and Drug Administration records.

Subpart B—General Policy

- 20.20 Policy on disclosure of Food and Drug Administration records.
- 20.21 Uniform access to records.
- 20.22 Partial disclosure of records.
- 20.23 Request for existing records.
- 20.24 Preparation of new records.
- 20.25 Retroactive application of regulations.
- 20.26 Indexes of certain records.
- 20.27 Submission of records marked as confidential.
- 20.28 Food and Drug Administration determinations of confidentiality.
- 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.
- 20.30 Food and Drug Administration Freedom of Information Staff.
- 20.31 Retention schedule of requests for Food and Drug Administration records.
- 20.32 Disclosure of Food and Drug Administration employee names.
- 20.33 Form or format of response.
- 20.34 Search for records.

Subpart C—Procedures and Fees

- 20.40 Filing a request for records.
- 20.41 Time limitations.
- 20.42 Aggregation of certain requests.
- 20.43 Multitrack processing.
- 20.44 Expedited processing.
- 20.45 Fees to be charged.
- 20.46 Waiver or reduction of fees.
- 20.47 Situations in which confidentiality is uncertain.
- 20.48 Judicial review of proposed disclosure.
- 20.49 Denial of a request for records.
- 20.50 Nonspecific and overly burdensome requests.
- 20.51 Referral to primary source of records.

- 20.52 Availability of records at National Technical Information Service.
- 20.53 Use of private contractor for copying.
- 20.54 Request for review without copying.
- 20.55 Indexing trade secrets and confidential commercial or financial information.

Subpart D—Exemptions

- 20.60 Applicability of exemptions.
- 20.61 Trade secrets and commercial or financial information which is privileged or confidential.
- 20.62 Inter- or intra-agency memoranda or letters.
- 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.
- 20.64 Records or information compiled for law enforcement purposes.
- 20.65 National defense and foreign policy.
- 20.66 Internal personnel rules and practices.
- 20.67 Records exempted by other statutes.

Subpart E—Limitations on Exemptions

- 20.80 Applicability of limitations on exemptions.
- 20.81 Data and information previously disclosed to the public.
- 20.82 Discretionary disclosure by the Commissioner.
- 20.83 Disclosure required by court order.
- 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.
- 20.85 Disclosure to other Federal government departments and agencies.
- 20.86 Disclosure in administrative or court proceedings.
- 20.87 Disclosure to Congress.
- 20.88 Communications with State and local government officials.
- 20.89 Communications with foreign government officials.
- 20.90 Disclosure to contractors.
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Subpart F—Availability of Specific Categories of Records

- 20.100 Applicability; cross-reference to other regulations.
- 20.101 Administrative enforcement records.
- 20.102 Court enforcement records.
- 20.103 Correspondence.
- 20.104 Summaries of oral discussions.
- 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.
- 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.