

§ 19.45

(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 specific party or parties in which the United States is a party or has a direct and substantial interest and in which

21 CFR Ch. I (4–1–01 Edition)

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

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- 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.

Subpart C—Procedures and Fees

- 20.40 Filing a request for records.
- 20.41 Time limitations.
- 20.42 Fees to be charged.
- 20.43 Waiver or reduction of fees.
- 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.
- 20.45 Situations in which confidentiality is uncertain.
- 20.46 Judicial review of proposed disclosure.
- 20.47 Denial of a request for records.
- 20.48 Nonspecific and overly burdensome requests.
- 20.49 Referral to primary source of records.
- 20.50 Availability of records at National Technical Information Service.
- 20.51 Use of private contractor for copying.
- 20.52 Request for review without copying.
- 20.53 Indexing trade secrets and confidential commercial or financial information.