

Food and Drug Administration, HHS

§ 20.1

- 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.
- 20.91 Use of data or information for administrative or court enforcement action.

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.
- 20.107 Food and Drug Administration manuals.
- 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.
- 20.109 Data and information obtained by contract.
- 20.110 Data and information about Food and Drug Administration employees.
- 20.111 Data and information submitted voluntarily to the Food and Drug Administration.
- 20.112 Voluntary drug experience reports submitted by physicians and hospitals.
- 20.113 Voluntary product defect reports.
- 20.114 Data and information submitted pursuant to cooperative quality assurance agreements.
- 20.115 Product codes for manufacturing or sales dates.
- 20.116 Drug and device listing information.

- 20.117 New drug information.
- 20.118 Advisory committee records.
- 20.119 Lists of names and addresses.
- 20.120 Records available in Food and Drug Administration Public Reading Rooms.

AUTHORITY: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582; 21 U.S.C. 321-393, 1401-1403; 42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1.

SOURCE: 42 FR 15616, Mar. 22, 1977, unless otherwise noted.

Subpart A—Official Testimony and Information

§ 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any

§ 20.2

other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

§ 20.2 Production of records by Food and Drug Administration employees.

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpoena duces tecum or by any other writing, shall be handled pursuant to the procedures established in subpart B of this part, and shall comply with the rules governing public disclosure established in subparts C, D, E, and F of this part and in other regulations cross-referenced in § 20.100(c).

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

§ 20.3 Certification and authentication of Food and Drug Administration records.

(a) Upon request, the Food and Drug Administration will certify the authenticity of copies of records that are requested to be disclosed pursuant to this part or will authenticate copies of records previously disclosed.

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration,

21 CFR Ch. I (4-1-14 Edition)

12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 76 FR 31469, June 1, 2011]

Subpart B—General Policy

§ 20.20 Policy on disclosure of Food and Drug Administration records.

(a) The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all Food and Drug Administration records shall be made available for public disclosure.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records have been shown.

(d) Under § 21.71 of this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be requested when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 21.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so retrieved or a person acting on his behalf; and

(3) The disclosure is one that is discretionary, i.e., not required under this part.

(e) “Record” and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained by the agency in any format, including an electronic format.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]