Subpart B—General Policy

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

(a) The Food and Drug Administration (FDA) 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 FDA records shall be made available for public disclosure. FDA will withhold requested information only if:

(1) The Agency reasonably foresees that disclosure would harm an interest protected by an exemption described in this part; or

(2) Disclosure is prohibited by law.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless of 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 part 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.

(f) FDA will establish procedures for identifying records of general interest or use to the public that are appropriate for public disclosure, and for posting and indexing such records in a publicly accessible electronic format.

[87 FR 55911, Sept. 13, 2022]

§ 20.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information, and in § 20.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 7.87(c) of this chapter for section 305 hearing records, in § 20.80(b) regarding certain limitations on exemptions, in § 20.103(b) for certain correspondence, and in § 20.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

(c) Disclosure of a record about an individual, as defined in § 21.3(a) of this chapter, that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter, shall be subject to the special requirements of part 21 of this chapter. Disclosure of such a record to an individual who is the subject of the record does not invoke the rule established in this section that such records shall be made available for disclosure to all members of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9037, Mar. 3, 1989]

§ 20.22 Partial disclosure of records.

(a) If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

(b)(1) Whenever information is deleted from a record that contains both

disclosable and nondisclosable information, the amount of information deleted shall be indicated on the portion of the record that is made available, unless including that indication would harm an interest protected by an exemption under the Freedom of Information Act.

(2) When technically feasible, the amount of information deleted shall be indicated at the place in the record where the deletion is made.

(3) The exemption(s) under which the information has been deleted shall be noted at the site of the deletion.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003; 87 FR 55911, Sept. 13, 2022]

§ 20.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Electronic availability and indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, and, as required, copies of electronic records shall be made available for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(4) Records that have been released to any person in response to a Freedom of Information request, and that:

(i) The Agency has determined have become, or are likely to become, the subject of subsequent Freedom of Information requests for substantially the same records; or

(ii) Have been requested three or more times under the Freedom of Information Act.

(b) Each such record and index will be made available by accessing the Agency's website at *https://www.fda.gov*. A printed copy of each index is available by writing or visiting the Freedom of Information Staff's address on the Agency's website at *https://www.fda.gov*.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003; 76 FR 31469, June 1, 2011; 79 FR 68114, Nov. 14, 2014; 87 FR 55911, Sept. 13, 2022]