

Food and Drug Administration, HHS

§ 20.26

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 re-

produce 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