

§ 10.20 [Amended]

■ 2. Section 10.20 *Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure* is amended in paragraph (c)(6) by removing the last sentence and in paragraph (j)(2)(ii) by removing “§ 20.46” and by adding in its place “§ 20.48”.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 3. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.61 [Amended]

■ 4. Section 14.61 *Transcripts of advisory committee meetings* is amended in paragraph (d) by removing “§ 20.42” and by adding in its place “§ 20.45” and by removing “§ 20.51” and by adding in its place “§ 20.53”.

PART 20—PUBLIC INFORMATION

■ 5. The authority citation for 21 CFR part 20 continues to read as follows:

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.

■ 6. Section 20.20 is amended by adding paragraph (e) to read as follows:

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

* * * * *

(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.

■ 7. Section 20.22 is amended by redesignating the existing paragraph as paragraph (a) and by adding paragraph (b) to read as follows:

§ 20.22 Partial disclosure of records.

(a) * * *

(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.

■ 8. Section 20.26 is amended by adding paragraph (a)(4) and by revising paragraph (b) to read as follows:

§ 20.26 Indexes of certain records.

(a) * * *

(4) Records that have been released to any person in response to a Freedom of Information request and that the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available through the Internet at <http://www.fda.gov>. A printed copy of each index is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room in rm. 12A–30 at the same address.

§ 20.27 [Amended]

■ 9. Section 20.27 *Submission of records marked as confidential* is amended by removing the phrase “to review them pursuant to the procedures established in § 20.44,”

§ 20.28 [Amended]

■ 10. Section 20.28 *Food and Drug Administration determinations of confidentiality* is amended by removing the phrase “or by a written determination pursuant to the procedure established in § 20.44”.

§ 20.29 [Amended]

■ 11. Section 20.29 *Prohibition on withdrawal of records from Food and Drug Administration files* is amended by removing the phrase “Except pursuant to the procedures established in § 20.44 for presubmission review of records, no” from the first sentence and by adding in its place the word “No”.

■ 12. Subpart B is amended by adding §§ 20.33 and 20.34 to read as follows:

§ 20.33 Form or format of response.

(a) The Food and Drug Administration shall make reasonable efforts to provide a record in any requested form or format if the record is readily reproducible by the agency in that form or format.

(b) If the agency determines that a record is not readily reproducible in the requested form or format, the agency may notify the requester of alternative forms and formats that are available. If the requester does not express a preference for an alternative in response to such notification, the agency may provide its response in the form and format of the agency's choice.

§ 20.34 Search for records.

(a) In responding to a request for records, the Food and Drug Administration shall make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

(b) The term “search” means to review, manually or by automated means, agency records for the purpose of locating those records that are responsive to the request.

■ 13. Section 20.40 is amended by revising paragraph (a) to read as follows:

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, or by faxing it to 301–443–1726. All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

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■ 14. Section 20.41 is amended by revising the introductory text of paragraph (b) and paragraph (b)(3), in paragraph (b)(2) by removing “§ 20.45” and by adding in its place “§ 20.47”, and by adding paragraph (c) to read as follows:

§ 20.41 Time limitations.

* * * * *

(b) Within 20 working days (excluding Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial.

* * * * *

(3) (i) In unusual circumstances, the agency may extend the time for sending the letter for an additional period.

(A) The agency may provide for an extension of up to 10 working days by providing written notice to the requester setting out the reasons for the extension and the date by which a determination is expected to be sent.

(B) The agency may provide for an extension of more than 10 working days by providing written notice to the requester setting out the reasons for the extension. The notice also will give the requester an opportunity to limit the