

Subpart E—Procedures for Requests for Amendment of Records

§21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has already been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with §21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with §21.44.

(d) Written acknowledgement of the receipt of a request to amend a record

shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§21.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

(1) Amend any portion of the record which the agency has determined, based upon a preponderance of the evidence, is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete, and, in accordance with paragraph (d)(3) of this section, inform the individual and previous recipients of the record that has been amended of the amendment.

(2) Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Except as provided in §21.32, such refusal may only be issued by the Associate Commissioner for Public Affairs or his or her designate.

(3) Where another agency was the source of and has control of the record, refer the request to that agency.

(b) The agency may, for good cause, extend the period for taking action an additional 30 working days if notice is provided to the individual explaining the circumstances of the delay.

(c) The officials charged with reviewing a record to determine how to respond to a request to amend it, shall assess its accuracy, relevance to a Food and Drug Administration purpose, timeliness, or completeness. The determination shall be made in the light of the purpose for which the records or system is used, the agency's need for the record, and the possible adverse consequences to the individual

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from the record if not amended. Whenever the Food and Drug Administration receives a request for deletion of a record, or portions of a record, it shall consider anew whether the contested information in the record is relevant and necessary to a Food and Drug Administration purpose.

(d) If the Food and Drug Administration agrees with an individual's request, it shall take the following actions:

(1) So inform the individual in writing.

(2) In accordance with statute, regulation, or procedure, amend the record to make it accurate, relevant to a Food and Drug Administration purpose, timely, or complete, making note of the date and fact of the amendment.

(3) If an accounting was made under § 21.71(d) of a disclosure of the record under § 21.71(a), provide a copy of the record as amended, to all previous recipients of the record.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§ 21.52 Administrative appeals of refusals to amend records.

(a) If an individual disagrees with a refusal under § 21.51(a)(2) to amend a record, he or she may appeal that refusal to the Commissioner of Food and Drugs, Rm. 14-71, 5600 Fishers Lane, Rockville, MD 20857.

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

(1) Of his decision and the reasons for it.

(2) Of the individual's right to file with the Food and Drug Administration a concise statement of the individual's reasons for disagreeing with the agency's decision not to amend the record as requested.

(3) That the statement of disagreement will be made available to all persons listed in an accounting as having previously received the record and any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the state-

ment of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

(4) That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with § 21.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985]

§ 21.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under § 21.52(b)(2), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under § 21.70 or § 21.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be subject to a request for amendment under § 21.50.

(c) If an accounting was made under § 21.71(d) and (e) of a disclosure of the record under § 21.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.