

§ 21.52

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 statement 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

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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.

§ 21.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the record, and

(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under § 21.71 (d) and (e) of the disclosure of the record under § 21.71(a), inform all previous recipients of the record about