

§ 21.33

for personnel records that are maintained by the operating offices of the Food and Drug Administration in which employees work:

(1) An employee shall upon request be told whether records about him are maintained. An employee shall be given access to records about himself that are subject to this paragraph in response to an oral or written request and through informal procedures, rather than the procedures specified in §§ 21.40 through 21.43.

(2) Employee identity may be verified, if necessary, by an FDA ID card rather than in accordance with § 21.44.

(3) Generally no fee shall be charged for records requested under this paragraph. However, in cases where the records requested are voluminous, a fee may be charged in accordance with § 21.45.

(4) Records that are subject to this paragraph shall be available for access to an individual, except to the extent that access is refused by the Associate Commissioner for Management and Operations or his or her designate on the grounds that the record is subject to an exemption under § 21.61 or 5 CFR 297.111.

(5) Requests under the Privacy Act for amendment of records subject to this paragraph should be directed to the Director, Division of Human Resources Management (HFA-400). Such requests shall be reviewed in accordance with subpart E of this part. Refusal to amend a record subject to this paragraph (d)(5) shall only be made by the Associate Commissioner for Management and Operations or his or her designate.

(6) Appeals of refusals under paragraph (d) (4) or (5) of this section may be made to the Commissioner of Food and Drugs, except where the Associate Commissioner for Management and Operations or his or her designate indicates with his or her refusal that the appeal should be made to the Office of Personnel Management.

(7) Disclosures of records subject to this paragraph are subject to subpart G of this part.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

21 CFR Ch. I (4-1-08 Edition)

§ 21.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records about himself in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The Food and Drug Administration may apply the following special procedures in disclosing medical records to an individual:

(1) The agency may review the records to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be disclosed to him. If it is determined that disclosure is very likely to have an adverse effect on the individual, he may be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) The availability of the record may be subject to any procedures for disclosure to an individual of medical records about himself under part 20 of this chapter, in addition to or in lieu of the procedures in paragraph (b)(1), that are not inconsistent with § 21.41(f).

Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

§ 21.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record about him exists, requests that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy