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to any record is denied wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

(c) If a request for a copy of the records will result in a fee of more than $25, the letter shall specify or estimate the fee involved. Where the individual has requested a copy of any records about him and copying the records would result in a fee of over $50, the Food and Drug Administration shall require advance deposit as well as payment of any amount not yet received as a result of any previous request by the individual for a record about himself, under this subpart or part 20 of this chapter (the public information regulations) before the records are made available. If the fee is less than $50, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request by the individual for a record about himself under this subpart or part 20 of this chapter.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§21.43 Access to requested records.

(a) Access may be granted to requested records by:

(1) Mailing a copy of the records to the requesting individual, or

(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office of the FDA Privacy Act Coordinator, at the Division of Freedom of Information Public Reading Room at the address shown in §20.30 of this chapter, or at any Food and Drug Administration field office, listed in part 5, subpart M of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 69 FR 17290, Apr. 2, 2004; 76 FR 31470, June 1, 2011]

§21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the Food and Drug Administration to determine his identity. The identification required shall be suitable considering the nature of the records sought. No identification shall be required to receive access to information that is required to be disclosed to any member of the public under part 20 of this chapter (the public information regulations).

(b) An individual who appears in person for access to records about himself shall be required to provide at least one document to identify himself, e.g., driver's license, passport, or alien or voter registration card to verify his identity. If an individual does not have any such document or requests access to records about himself without appearing in person under circumstances in which his identity cannot be verified from the request itself, he shall be required to certify in writing that he is the individual he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(c) In making requests under § 21.75, a parent of a minor child or legal guardian of an incompetent individual may be required to verify his relationship to the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed $25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the ''Food and Drug Administration,'' and shall be sent to the Accounting Branch (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds $50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

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