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confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§ 21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under § 21.61, an individual may nevertheless make a request under § 21.40 for notification concerning whether any records about him exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section;

(1) May be given access to the records where available under part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§ 21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of any right, benefit, or privilege to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. An individual given access to a record under this paragraph (b)(2) is not entitled to seek amendment under subpart E of this part. The FDA may refuse to disclose a record that would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished on or after September 27, 1975. Any individual refused access to a record that would reveal a confidential source shall be advised in a general

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way that the record contains information that would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under § 20.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under § 21.61.

Subpart G—Disclosure of Records in Privacy Act Record Systems to Persons Other Than the Subject Individual

§ 21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.

(a) A record about an individual which is contained in a Privacy Act Record System may be disclosed:

(1) To the individual who is the subject of the record, or his legal guardian under § 21.75;

(2) To a third party pursuant to a written request by, or within a written consent of, the individual to whom the record pertains, or his legal guardian under § 21.75;

(3) To any person:

(i) Where the names and other identifying information are first deleted, and under circumstances in which the recipient is unlikely to know the identity of the subject of the record;

(ii) Where disclosure is required by part 20 of this chapter (the public information regulations); or

(4) Within the Department of Health and Human Services to officers and employees who have a need for the record in the performance of their duties in connection with the laws administered and enforced by the Food and Drug Administration or that govern the agency. For purposes of this section, officers or employees of the Department shall include the following categories of individuals, who shall thereafter be subject to the same restrictions with respect to disclosure as any Food and

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Drug Administration employee; Food and Drug Administration consultants and advisory committees, State and local government employees for use only in their work with the Food and Drug Administration, and contractors and their employees to the extent that the records of such contractors are subject to the requirements of this part under §21.30.

(b) No accounting is required for any disclosure or use under paragraph (a) of this section.

§21.71 Disclosure of records in Privacy Act Record Systems; accounting required.

(a) Except as provided in §21.70, a record about an individual that is contained in a Privacy Act Record System shall not be disclosed by any method of communication except under any of the following circumstances, which are subject to the limitations of paragraphs (b) and (c) of this section and to the accounting requirement of paragraph (d) of this section:

(1) To those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

(2) Required under section 552 of the Freedom of Information Act;

(3) For a routine use as described in the routine use section of each specific system notice;

(4) To the Bureau of Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13 of the U.S. Code;

(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and that the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives and Records Administration of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the U.S. Government, or to the Archivist of the United States or his or her designee for evaluation to determine whether the record has such value;

(7) To another agency or to an instrumentality of any government jurisdiction

within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such individual;

(9) To either House of Congress or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) To the Comptroller General, or any of his or her authorized representatives in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction; or

(12) To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d)). (This "Special Disclosure" statement does not apply to any FDA system of records.)

(b) The Food and Drug Administration may in its discretion refuse to make a disclosure permitted under paragraph (a) of this section, if the disclosure would in the judgment of the agency, invade the privacy of the individual or be inconsistent with the purpose for which the information was collected.

(c) The Food and Drug Administration may require any person requesting a disclosure of a record under paragraph (a) of this section to provide:

(1) Information about the purposes to which the disclosed record is to be put, and

(2) A written statement certifying that the record will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

Under 5 U.S.C. 552a(i)(3), any person who knowingly or willfully requests or