

**§ 21.3 Definitions.**

As used in this part:

(a) *Individual* means a natural living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. Individual does not include sole proprietorships, partnerships, or corporations engaged in the production or distribution of products regulated by the Food and Drug Administration or with which the Food and Drug Administration has business dealings. Any such business enterprise that is identified by the name of one or more individuals is not an individual within the meaning of this part. Employees of regulated business enterprises are considered individuals. Accordingly, physicians and other health professionals who are engaged in business as proprietors of establishments regulated by the Food and Drug Administration are not considered individuals; however, physicians and other health professionals who are engaged in clinical investigations, employed by regulated enterprises, or the subjects of records concerning their own health, e.g., exposure to excessive radiation, are considered individuals. Food and Drug Administration employees, consultants, and advisory committee members, State and local officials, and consumers are considered individuals.

(b) *Records about individuals* means items, collections, or groupings of information about individuals contained in Privacy Act Record Systems, including, but not limited to education, financial transactions, medical history, criminal history, or employment history, that contain names or personal identifiers.

(c) *Privacy Act Record System* means a system of records about individuals under the control of the Food and Drug Administration from which information is retrieved by individual names or other personal identifiers. The term includes such a system of records whether subject to a notice published by the Food and Drug Administration, the Department, or another agency. Where records are retrieved only by personal identifiers other than individual names, a system of records is not a Privacy Act Record System if the Food and Drug Administration cannot, by

reference to information under its control, or by reference to records of contractors that are subject to this part under § 21.30, ascertain the identity of individuals who are the subjects of the records.

(d) *Personal identifiers* includes individual names, identifying numbers, symbols, or other identifying designations assigned to individuals. *Personal identifiers* does not include names, numbers, symbols, or other identifying designations that identify products, establishments, or actions.

(e) *Personnel records* means any personal information maintained in a Privacy Act Record System that is needed for personnel management programs or processes such as staffing, employee development, retirement, and grievances and appeals.

(f) *Department* means Department of Health and Human Services.

**§ 21.10 Policy concerning records about individuals.**

Information about individuals in Food and Drug Administration records shall be collected, maintained, used, and disseminated so as to protect the right to privacy of the individual to the fullest possible extent consistent with laws relating to disclosure of information to the general public, the law enforcement responsibilities of the agency, and administrative and program management needs.

**Subpart B—Food and Drug Administration Privacy Act Record Systems****§ 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.**

(a) The Food and Drug Administration shall issue in the FEDERAL REGISTER on or before August 30 of each year a notice concerning each Privacy Act Record System as defined in § 21.3(c) that is not covered by a notice published by the Department, the Office of Personnel Management, or another agency.

(b) The notice shall include the following information:

(1) The name and location(s) of the system.

## §21.21

(2) The categories of individuals about whom records are maintained in the system.

(3) The categories of records maintained in the system.

(4) The authority for the system.

(5) Each routine use of the records contained in the system (i.e., use outside the Department of Health and Human Services that is compatible with the purpose for which the records were collected and described in the notice) including the categories of users and the purposes of such use.

(6) The policies and practices of the Food and Drug Administration regarding storage, retrievability (i.e., how the records are indexed and what intra-agency uses are made of the records), access controls, retention, and disposal of the records in that system.

(7) The title and business address of the official who is responsible for the system of records.

(8) The notification procedure, i.e., the address of the FDA Privacy Act Coordinator, whom any individual can contact to seek notification whether the system contains a record about him/her.

(9) The record access and contest procedures, which shall be the same as the notification procedure except that a reference shall be included to any exemption from access and contest.

(10) Where any records in the system are subject to an exemption under §21.61, a reference to this exemption.

(11) The categories of sources of records in the system.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

### §21.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the designated Department official, the Office of Management and Budget (Information Systems Division), and the Congress of proposals to change or establish Privacy Act Record Systems in accordance with procedures of the Department and the Office of Management and Budget.

(b) The Food and Drug Administration shall issue a notice, in accordance with paragraph (d) of this section and

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

§21.20(b), of any change in a Privacy Act Record System which:

(1) Increases the number or types of individuals about whom records are maintained;

(2) Expands the type or amount of information about individuals that is maintained;

(3) Increases the number of categories of agencies or other persons who may have access to those records;

(4) Alters the manner in which the records are organized so as to change the nature or scope of those records, such as the combining of two or more existing systems;

(5) Modifies the way in which the system operates or its location(s) in a manner that alters the process by which individuals can exercise their rights under this part, such as the ways in which they seek access or request amendment of a record; or

(6) Changes the equipment configuration on which the system is operated so as to create the potential for greater access, such as adding a telecommunications capability.

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and §21.20(b).

(d) Notices under paragraphs (b) and (c) of this section shall be published in the FEDERAL REGISTER for comment at least 30 days prior to implementation of the proposed changes or establishment of new systems. Interested persons shall have the opportunity to submit written data, views, or arguments on such proposed new uses or systems.

## Subpart C—Requirements for Specific Categories of Records

### §21.30 Records of contractors.

(a) Systems of records that are required to be operated, or as a matter of practical necessity must be operated, by contractors to accomplish Food and Drug Administration functions, from which information is retrieved by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C.