

§21.3

21 CFR Ch. I (4–1–08 Edition)

Administration, except as provided in §21.32. Such records are subject to regulations of the Office of Personnel Management in 5 CFR parts 293, 294, and 297.

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

§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 in-

cludes 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