§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.
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
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§ 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. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in §21.71 or for maintenance of a system of records without notice as required in §21.20.

(b) A contract is considered to accomplish a Food and Drug Administration function if the proposal or activity it supports is principally operated on behalf of and is under the direct management of the Food and Drug Administration. Systems of records from which information is retrieved by individual names or other personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and

§ 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 §21.20(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.