PROPOSED RULES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration

[21 CFR Parts 4, 7 ]

Docket No. 75N-0212

RECORDS ABOUT INDIVIDUALS

Proposed Rulemaking To Implement the Privacy Act of 1974

The Commissioner of Food and Drugs is proposing to carry out the Privacy Act with respect to records of records maintained by the Food and Drug Administration from which information is retrieved by the name of the individual or other personal identifier. Interested persons have until September 26, 1975, to submit comments to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

The Privacy Act imposes certain requirements on each Federal agency that maintains systems of records from which information is retrieved by the names of individuals and other personal identifiers. The purpose of the act is to provide certain safeguards against invasions by Federal agencies of personal privacy. The act requires that individuals be given access to, and opportunity to request amendment of, records about themselves in these systems, unless a system is by regulation exempted from such access and amendments. It also restricts disclosures of records in such systems to third persons. In addition, it regulates Federal agency information collection and maintenance practices, e.g., by prohibiting collection and maintenance of records about individuals that are not relevant and necessary to an agency purpose. Finally, the act provides both civil and criminal remedies for violation of its safeguards.

For these reasons, the Joint Board seeks exemptions from the requirement of subsection (e) (1) and (2).

Subsection (e) (4) (1) of the Privacy Act of 1974 requires the publication of the categories of sources of records in each system of records. The Joint Board believes that publication of said requirement would seriously impair its ability to obtain information from such sources for the following reasons. Revealing such categories of sources could disclose investigative techniques and procedures and could undermine the Joint Board's ability to provide information because of fear of reprisal, or fear of breaches of promises of confidentiality. For these reasons, the Joint Board seeks exemptions from the requirement of subsection (e) (4) (1).

FOREST D. MONTGOMERY,
Acting Chairman, Joint Board for the Enrollment of Actuaries

[FR Doc. 75-22400 Filed 8-28-75; 8:14 am]

FEDERAL REGISTER OF DECEMBER 24, 1974 (39 FR 44602), IMPLEMENT THE FREEDOM OF INFORMATION ACT (5 U.S.C. 552). THE PROPOSED RULES ARE TO BE ACTIONED IN THE PROPOSED REGULATIONS TO PROVIDE FOR THE MAINTENANCE OF RECORDS ABOUT INDIVIDUALS THAT ARE PROPERLY MAINTAINED.

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PROPOSED RULES

30839

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Consistent with the Privacy Act, the Food and Drug Administration will continue to favor the "no discovery" rule favoring maximum disclosure of records to the public. In many cases this may be accomplished by deletions of names and other information which would identify an individual or a group of individuals that would identify individuals is deleted, a record is no longer subject to any Privacy Act restrictions on disclosure.

10. Section 4.83 of the public information regulations are being amended in Subpart G to prohibit any court-ordered disclosures of exempt records, is amended to include a new paragraph implementing the Privacy Act requirement (5 U.S.C. 552a(b)(6)(B) that agencies "make reasonable efforts to serve notice on an individual when any record on such individual is made to any person under compulsory legal process when such records are not subject to the Privacy Act provision (5 U.S.C. 552a(b)(6)(B) that a court-ordered disclosure of personal records about an individual is required to be made public." The requirement is construed as only being applicable to court-ordered disclosures of records about individuals that are not required to be time a record notice of disclosure is made public. The requirement will apply to all such records about individuals, whether or not a record is contained in a Privacy Act Record System. It therefore being implemented by amendment of 21 CFR Part 4 (the public information regulations), rather than in proposed 21 CFR Part 7. It is not clear whether the application of this provision for individual notice of a court-ordered disclosure of personal records that are not contained in Privacy Act Record Systems is required by the Privacy Act. This requirement of notice of disclosure does not apply when identifying information is deleted prior to the disclosure.

11. A new §4.119 is proposed to be added to the public information regulations (21 CFR 4.119). This indirect amendment of the Freedom of Information Act has a lesser impact on the Freedom of Information Act of personal records in Privacy Act Record Systems that are not required to be released to the public because they fall within the Freedom of Information Act's exemptions for interagency or intragency memoranda (5 U.S.C. 552(b)(7)) or for certain investigatory records compiled for law enforcement purposes (5 U.S.C. 552(b)(7)). The public information regulations are being amended in § 4.83(b) (21 CFR 4.83(b)) to prohibit discretionary disclosure of personal records about individuals contained in Privacy Act Record Systems except in accordance with the Privacy Act regulations (21 CFR Part 7, Subpart G).

PROPOSED PRIVACY REGULATIONS

13. To implement the Privacy Act, a new Part 7, Protection of Privacy, is proposed to be established in Title 21 of the Code of Federal Regulations.

14. New § 7.1(a) explains when requests by individuals for records about themselves are governed by 21 CFR Part 4 (the public information regulations) and when they are governed by proposed 21 CFR Part 7 (the privacy regulations).

15. Most requirements of the Privacy Act only apply to "records" about "individuals" contained in "systems of records", as these terms are defined in the act (5 U.S.C. 552a(a)):

(a) Definitions—For purposes of this section—

(1) "individual" means a citizen of the United States or an alien lawfully admitted for permanent residence;

(2) the term "individual" means a citizen of the United States or an alien lawfully admitted for permanent residence;

(3) the term "record" means any item, collection, or grouping of information about an individual that is maintained by an agency, and that is accessible to the agency by name or by any identifying number, symbol, or other designation.

FEDERAL REGISTER, VOL. 40, NO. 167—WEDNESDAY, AUGUST 27, 1975
criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint or voice-print or a photograph.

(5) the term "system of records" means a group of any records under the control of any agency from which information is retrieved by the use of identifying number, symbol, or other identifying particular assigned to the individual.

The meaning and effect of these definitions are discussed in detail in the OMB Guidelines (40 FR 28851-52).

16. Proposed §7.3(a) defines "individual" to mean any natural living person who is a citizen or permanent resident. In accordance with the OMB Guidelines (40 FR 28851), the term "individual" is defined to exclude business enterprises, including sole proprietorships, engaged in distribution of products regulated by the Food and Drug Administration or which have business dealings with the agency. Congress did not intend the Privacy Act to affect Government information systems and data banks with respect to businesses (Senate Report 92-1183, p. 59).

The effect of this definition is to make it clear that proposed 21 CFR Part 7 (the privacy regulations) does not provide business enterprises with any new rights of access to information in Food and Drug Administration files in addition to the rights now provided in 21 CFR Part 4 (the public information regulations). Furthermore, the definition of "individual" also makes clear that the new restrictions on disclosure proposed in 21 CFR Part 7, Subpart G, do not restrict disclosures, including discretionary disclosures under the Freedom of Information Act, of information about business enterprises that are not regarded as individuals.

In determining whether a particular record is subject to the Privacy Act, the Food and Drug Administration has followed the Principles, which call first, a determination whether the information being maintained is, in fact, personal in nature and, second, a review of the manner in which the information is used, to determine whether the individual is dealt with in a personal or in an "entrepreneurial" capacity (40 FR 28861). Proposed §7.3 explains the application of the term "individual" to several categories of subjects of many Food and Drug Administration records. The following are considered to be individuals: employees, retired business enterprises, physicians and other health professionals engaged in clinical investigations or other essentially personal or unique activities (but not as proprietors of regulated enterprises). Food and Drug Administration employees, consultants, advisory committee members, State and local officials, and consumers.

The definition of "individual" is limited to living persons because the Privacy Act does not provide any rights concerning records about decedents. The act does not authorize relatives and other interested persons to act on behalf of individuals who are the subjects of records after those individuals have died (OMB guidelines).

17. Proposed §7.3(b) defines the term "records about individuals" in the same way that the Privacy Act defines "record" (5 U.S.C. § 552(a)(4)). It should be noted that a record is only considered to be a record about an individual when it contains names or other information that would identify an individual. Thus, a document from which all individual information has been deleted would not be considered a "record" under the Privacy Act, and when disclosed in this form would not be subject to the restrictions on disclosure proposed in 21 CFR Part 7, Subpart G.

There are certain kinds of Food and Drug Administration records in which individuals are mentioned or listed in an impersonal way for entirely nonpersonal purposes that would not be considered records about individuals and would thus not be treated as Privacy Act Record Systems, no matter how they are stored or retrieved.

Among such records are:

a. Records about regulated enterprises or products in which an individual is named as the person to contact on a matter, or as the person who reported product information to the agency, are not considered records about individuals. Examples are the company contacts included in the drug registration and listing system (such information is not, however, retrieved by the individual's name); the Drug Defect Reporting System, which indexes names of pharmacists who reported drug defects; or a product registry system indexed by names of reporting establishments or physicians, rather than of patients.

b. Impersonal administrative management tools using Food and Drug Administration employees names for a purpose related to the administrative functions of the agency; or as the person who reported a product to the agency, are not considered records about individuals. Examples are in Food and Drug Administration Data Systems, which is used to compare planned field work with field work actually accomplished and which includes employee symbols and pay rates in order to calculate total expenditures of agency resources, use of employees' names as an index to locate laboratory notebooks concerning experiments or to identify productive employees; Individual Work Assignment systems identifying employees assigned to various tasks (e.g., inspection of certain establishments); and telephone directories giving name, title, organizational unit, home address, office number, and telephone number. To the extent that any administrative management records are used to make determinations about individuals, or include personal information about home addresses, they shall be regarded as personnel files subject to proposed §7.32 of the regulations (21 CFR 1.32) and covered by the Department notices for working level personnel files.

c. Information retrieval systems, whether or not developed by the Food and Drug Administration, that are used to facilitate location of information on a particular subject (such as research done on a particular substance) are not records about individuals. Examples are information contained in indexes to documents in Food and Drug Administration libraries; bibliographies appended to Food and Drug Administration documents; computerized information retrieval systems used to facilitate scientific review; data bases or lists maintained by the Food and Drug Administration.

d. Mailing lists and lists of individuals in an organization to be contacted or regulated matters are not records about individuals unless they are also developed by the agency to be used in some other way to make determinations about individuals, benefits, privileges, or interests that would not be considered personal identifiers (such as determining who may have the qualifications and interest to serve as a consultant to the Food and Drug Administration on a matter) or unless there is a likelihood that the personal identifiers would reveal personal information, which is not likely for any mailing or contact list that the Food and Drug Administration maintains. Proposed §4.1(d) defines "public information retrievals" (21 CFR 4.119) would govern the availability of name and address lists to the public and §4.63 of the public information regulations (21 CFR 4.123) bars disclosure of such lists that would constitute a clearly unwarranted invasion of personal privacy.

18. In lieu of "system of records," the statutory term of art for Government documents that are generally subject to the Privacy Act, proposed §7.3(c) uses the term "Privacy Act Record System.

As explained in the OMB Guidelines (40 FR 28852), the OMB, in accordance with the principles, rules of the Privacy Act do not give individuals rights of access to records that include incidental references to them where the agency does not maintain the records and retrieve them by reference to the names or other personal identifiers of the individuals. Thus, the Privacy Act does not give an individual a right of access to information that the agency does not retrieve by reference to his name or other personal identifier but retrieves only by reference to some other name or symbol, or even the name or symbol of another individual.

The Food and Drug Administration rarely has occasion to file information by individual name, except for routine agency personnel and administrative management records files by employee name. Individual files are maintained sparingly. Most FDA records are retrieved by names or symbols of establishments or products, or by numbers of cases assigned by product sample num-
There are some administrative management systems that are used in part for impersonal management information purposes, such as keeping track of a normal expenditure to accomplish a task and in part to make determinations about individuals, such as denying a training request based on a record of expenditures showing that an individual has already had ample training. Such systems are considered working level personnel Privacy Act Record Systems only to the extent they are used in individual determinations.

NOTICE OF FDA PRIVACY ACT RECORD SYSTEMS

22. Subpart E of the proposed regulations (21 CFR Part 7, Subpart B) prescribes procedures for publishing notice of the existence of specific Food and Drug Administration Privacy Act Record Systems other than those covered by notices published by the Department, the Civil Service Commission, or another agency. Procedures for notice of new systems, or changes in systems, are also proposed.

SPECIFIC CATEGORIES OF RECORDS

23. Subpart C of the proposed regulations (21 CFR Part 7, Subpart C) prescribes specific requirements for records of contractors (§7.30), records stored by the General Services Administration, and archival records (§7.31), personnel records (§7.32), and medical records (§7.33).

24. Record systems maintained by contractors under contracts with the Food and Drug Administration may be subject to the Privacy Act under proposed §7.30 of the regulations (21 CFR 7.30). If a Privacy Act Record System is "under the control of any agency" it is subject to the act even if the contractor acts as custodian of the records (5 U.S.C. 552a(a) (5)). The act also specifically provides that "when an agency provides a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of section 552a(a) to be carried out by the contractor." (5 U.S.C. 552a(m)). The OMB Guidelines (40 FR 28976-76) explain that contractors' records are not ordinarily subject to the act, unless the contract specifies that the contractor shall maintain a system of records indexed by individual name or other personal identifier. However, there may be some instances in which the contract of necessity will involve establishment of such a system even though the contract does not expressly so provide.

A contract must have been entered into to accomplish a Food and Drug Administration function for it to be subject to the Privacy Act. Where accomplishment of a Food and Drug Administration function is incidental to other activities of the contractor, the contract is not considered to be for a Food and Drug Administration function. For example, records of State and local government agencies under contract with the Food and Drug Administration concerning

FEDERAL REGISTER, VOL. 40, NO. 167—WEDNESDAY, AUGUST 27, 1975
PROPOSED RULES

28. Proposed Subpart E of the regulations (21 CFR Part 7, Subpart E) prescribes procedures for an individual who has obtained access to records to request amendment of records he believes are not accurate, relevant, to a Food and Drug Administration purpose, timely, or complete. Proposed Subpart E implements 5 U.S.C. 552a(d) (2), (3), and (4) and (f) (4).

29. Proposed § 7.50(b) (1) of the regulations (21 CFR 7.50(b) (1)), makes clear that the Privacy Act is not intended to permit amendment of records that have been presented as evidence in the course of judicial or quasi-judicial or quasi-administrative proceedings. Such records could be corrected only through established procedures consistent with the adversary process. Nor was the Privacy Act intended to provide a collateral attack upon determinations already reached in judicial or quasi-judicial proceedings. Thus, an individual may not invoke the Privacy Act to challenge a previous decision or decision upon a request to reopen a case, although the individual could challenge whether the agency has accurately recorded the conviction or the liability that a court or other tribunal imposed.

29. In some instances, issues that may arise under the Privacy Act with regard to the accuracy, relevance, timeliness, completeness of records will be similar to issues that can, or have been, raised in agency determinations on the underlying claim. In such a case, under proposed § 7.50(b) (2) of the regulations (21 CFR 7.50(a) (2)), the FDA may defer its final decision on a request to amend the record until completion of the proceedings to resolve the underlying claim if such proceeding provides a forum for resolving the issue concerning the records. The Privacy Act does not require the establishment of new mechanisms for assessing the accuracy of the records or for reconciling disputes where such capabilities exist and do, or can be modified to, conform to, the systems of records (OMB Guidelines, 40 FR 29355). This procedure is most likely to be used in personnel actions. For example, if an issue in an adverse personal action is whether an employee's work is satisfactory, and the employee's work is satisfactory, and the record maintained in personnel offices will generally be made available to the individual. The availability to an individual, or to other persons, of medical records from such records maintained in personnel offices shall be the responsibility of the agency which created or maintains the records.

PROPOSED RULES

30. All Federal systems of records about individuals from which information is retrieved by reference to an individual's name or other personal identifier are subject to certain requirements of the Privacy Act. Among these are the requirement of public notice of the existence of a system of records, the requirement of annual publication in the Federal Register of a memorandum describing the system, amendments to the system, and any other significant change in the system, the right of access by individuals to records maintained about them, and the right of individuals to have records corrected.

A specific exemption (subsection (k) (2)) is available for a system of records that is "investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (i) (1) or (2)." The basis for such a system is "the investigation, including reports of informants and investigators, and associated with an identifiable individual; or (G) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

A specific exemption (subsection (k) (2)) is available for a system of records that is "investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (i) (1) or (2)." The basis for such a system is "the investigation, including reports of informants and investigators, and associated with an identifiable individual; or (G) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

FEDERAL REGISTER, VOL. 40, NO. 167—WEDNESDAY, AUGUST 27, 1975
promise that the identity of the source would be held in confidence, or, prior to the effective date of this act, an implied promise that the identity of the source would be held in confidence.

There is also a specific exemption in subsection (k)(5) for:

Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

Under both the general exemption provision (subsection (j)(2)) and the specific exemption provision (subsection (k)(2)), exempted investigative records can be the subject of a judicial proceeding as well as of civil and criminal penalties. Both kinds of records that Congress contemplated are criminal in nature. Under some statutes, administered by the Food and Drug Administration, such as the biologics control and quarantine provisions of the Public Health Service Act, the only judicial sanctions are criminal penalties.

32. Proposed Subpart F of the regulations (21 CFR Part 7, Subpart F) exempts specific Food and Drug Administration Privacy Act Record Systems from several requirements of the Privacy Act to the extent that they contain investigatory material compiled for law enforcement purposes, including criminal law enforcement. Limitations on this exemption are also set forth in Subpart F.

33. Proposed § 7.60 of the regulations (21 CFR 7.60) states the policy of the Food and Drug Administration for record systems to be exempted from the Privacy Act to only the extent necessary to the conduct of law enforcement functions. This section also sets forth the authority and purpose for requesting the information from the agency, and specifies that the records subject to the Privacy Act exempt system are not seeking to exempt record systems from-the Privacy Act to the extent necessary to prevent interference with its investigatory and enforcement activities. The Commissioner of Food and Drugs has closely reviewed each of the agency’s record systems subject to the act to determine whether need exists for an exempting regulation and for which categories of records. The Commission’s exemption of particular provisions of the act from which systems may be exempted to determine which provisions need not be included in the exemption.

34. Under proposed § 7.61 of the regulations (21 CFR 7.61), an exemption is proposed for investigatory material contained in three Food and Drug Administration Privacy Act Record Systems: (a) Clinical Investigator Records; (b) Regulated Industry Employee Enforcement Records; and (c) Food and Drug Administration employee, contractor, and consultant security and contractor security and investigative records, which are part of a Department-wide system.

The exemption is based on both the general exemption for criminal law enforcement investigations in subsection (j)(2) and, to the extent that such exemption is applicable to any material, to the specific exemption for criminal law enforcement investigations in subsection (k)(2) and, to the extent that the general exemption provision is inapplicable to any material, to the specific exemption provision for other law enforcement purposes, including investigatory material compiled for law enforcement purposes, including criminal law enforcement, such as the biologics control and quarantine provisions of the Public Health Service Act. The latter exemption only applies to information compiled by the Food and Drug Administration in any criminal law enforcement investigations in which the conduct of the investigation would be prejudiced by procedures other than those required by the Privacy Act. The latter exemption only applies to information compiled by the Food and Drug Administration in any criminal law enforcement investigations in which the conduct of the investigation would be prejudiced by procedures other than those required by the Privacy Act.

These exemptions are essential to assure that Food and Drug Administration law enforcement investigations are not impeded by premature release of information about pending regulatory activities and the possible basis for action. The identity of confidential sources, the basis of investigatory lines of inquiry, and the techniques and procedures must be safeguarded. It is also essential that there be no interference with enforcement proceedings or the integrity of evidence presented in such proceedings. Any alleged inaccuracy in a FDA record can and should be challenged in the course of the regulatory proceeding for which the record was compiled, Constitutional principles and discovery rules in both civil and criminal actions will assure that individuals have sufficient opportunity to learn of the existence of and to challenge investigatory records used in these proceedings. In addition, the Food and Drug Administration has adopted rules (21 CFR Part 4, the public information regulations) that make many enforcement records available to members of the public, including individuals to whom they pertain.

The Food and Drug Administration's investigatory records are precisely the kinds of records that Congress contemplated could be exempted from the Privacy Act.
PROPOSED RULES

Individual access to certain law enforcement files could impair investigations, particularly those which involve complex and continuing patterns of behavior. It would alert subject persons that their activities are being scrutinized, and thus allow them time to take measures to prevent detection or action in a pending enforcement proceeding. (House Report 93-1416, p. 19).

33. The Food and Drug Administration is not proposing to take advantage of the full scope of the exemptions for law enforcement records systems. After careful reviewing the other provisions of the act, the agency does not at this time believe that exemptions from them is necessary to assure that its law enforcement activities are not hindered. For example, the Food and Drug Administration is not proposing to exempt any record systems from the provision requiring that agencies only maintain records that are relevant and necessary to accomplish an agency purpose required by statute or executive order. Of course, in law enforcement investigations, it is often necessary to collect information that may be only collaterally related to the particular laws enforced by the agency. With respect to an enforcement proceeding under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.), for example, it may be relevant and necessary to collect information that an individual violated a State law or other Federal law not enforced by the Food and Drug Administration, or that the individual who has provided documents submitted to the Food and Drug Administration had falsified documents submitted to the Food and Drug Administration or made material false in an enforcement action as an employee of a regulated enterprise.

36. The Regulated Industry Employee Enforcement Record System refers to that part of the agency's general record system, maintained by the Administrative Services Branch in headquarters, and comparable records in field offices that includes records that may be retrieved by an individual who, as an employee of a regulated enterprise, is subject to FDA enforcement action under statutes administered and enforced by the Food and Drug Administration or that govern the agency. This system does not include records indexed or retrieved by reference to names or other identifiers (e.g., Administrative File numbers) of regulated business enterprises doing business as corporations, partnerships, or sole proprietorships, or other person that are not considered "individuals" under the act. (See proposed § 7.3(a) of the regulations (21 CFR 7.3(a)).)

When a request is submitted for a record in the Regulated Industry Employee Enforcement Record System, the Food and Drug Administration will determine whether the record is subject to the regulatory status of the requester to determine whether the requester is a sole proprietor or another person not regarded as an "individual," for purposes of the Privacy Act. If the requester is an "individual," the agency will check the appropriate indexes to determine whether the requester's name or other identifier is included. If it is included, all records indexed by the requester's name will be retrieved and examined to determine whether they are disclosable. This will involve consideration of whether any part of the records must be deleted before disclosure because they contain trade secrets or other information protected by the Trade Secrets Act of 1905 or other statutes. Where the requester is an individual potentially subject to FDA enforcement action, the agency will also consider whether the information constitutes investigatory material compiled for law enforcement purposes that is exempt from disclosure under § 7.61 of the proposed privacy regulations (21 CFR 7.61). Investigatory material that is otherwise exempt shall be made available to an individual where the material has been the basis for denying him a right, benefit, or privilege, if material was created only under the specific law enforcement exemption provision of the act (5 U.S.C. 552(a)(2)).

Disclosure of Records in Privacy Act Record Systems to Third Parties

37. Proposed Subpart G of the regulations (21 CFR Part 7, Subpart G) would establish procedures for disclosing records contained in the Food and Drug Administration Privacy Act Record Systems. (21 CFR 7.61). The subpart would also require, in proposed § 7.71, which implements 5 U.S.C. 552(a)(6), that an accounting be kept of disclosures other than: Disclosures to the individual himself, to his guardian, or with his consent; disclosures with identifying information deleted; disclosures required by the public information regulations (21 CFR Part 4); or intra-agency uses by employees having a need for the record to perform their duties. Proposed § 7.72 establishes requirements for individual consent, which are adapted from proposed Department-wide requirements. Implementing § 7.5 U.S.C. 552(a)(6), § 7.73 of the regulations (21 CFR 7.73) records subject to the accounting requirement shall be reviewed prior to disclosure to determine accuracy, relevance, timeliness, and completeness, except where disclosure is required under the Freedom of Information Act or made to another agency that is itself subject to the Privacy Act.

Comment Period

38. While the Food and Drug Administration's customary practice is to allow 60 days for comment on proposed regulations, 30 days from the date of publication of this notice in the Federal Register (September 26, 1975) is allowed for comment on these proposed regulations. The shorter comment period is unavoidable because of the need to have promulgated final regulations by September 27, 1975, the effective date of section 3 of the Privacy Act.


PART 4—PUBLIC INFORMATION

1a. In Subpart B, § 4.20 is amended by revising paragraph (c) and by adding a new paragraph (d) to read as follows:

§ 4.20 Policy on disclosure of Food and Drug Administration records.

. . . . . .
(c) Except as provided in paragraphs (a) or (b) of this section, all nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records have been shown.

(d) In Subpart C, this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be required when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 7.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so requested or a person acting on his behalf; and

(3) The disclosure is one that is discretionary, i.e., not required under this part.

b. In Subpart B, § 4.21 is amended by adding a new paragraph (c) to read as follows:

§ 4.21 Uniform access to records.

. . . . . .
(c) Disclosure of a record about an individual, as defined in § 7.3(a) of this chapter, that is requested by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 7.3(c) of this chapter, shall be subject to the special requirements of Part 7 of this chapter. Disclosure of such a record to an individual who is the subject of the record shall not of itself make the record available for disclosure to all members of the public.

c. In Subpart C, § 4.40 is amended by adding a new paragraph (d) to read as follows:

§ 4.40 Filing a request for records.

. . . . . .
(d) A request by an individual, as defined in § 7.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of Part 7 of this chapter (the privacy regulations), if the record is requested by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 7.3(g) of this chapter.
(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

d. In Subpart E, § 4.60 is amended by adding a new paragraph (d) to read as follows:

§ 4.60 Applicability of limitations on exemptions.

**d.** In the case of a record in a Privacy Act Record System, as defined in § 7.5(c) of this chapter:

(1) The availability to an individual, as defined in § 7.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of Part 7 of this chapter (the privacy regulations) and shall not be subject to the exemptions in Subpart D of this chapter, except that where the system is exempt under § 7.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be governed by the special requirements of Part 7, Subpart G, of this chapter, except as provided in Part 7, Subpart G, of this chapter.

e. In Subpart E, § 4.62 is amended by adding a new paragraph (b) to read as follows:

§ 4.62 Discretionary disclosure by the Commissioner.

(b) Contained in a Privacy Act Record System where disclosure would constitute a clearly unwarranted invasion of personal privacy or is otherwise in violation of 5 U.S.C. 552(a), as applied in Part 7, Subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

f. In Subpart E, § 4.83 is amended by designating the existing text as paragraph (a) and adding new paragraphs (b) and (c) to read as follows:

§ 4.83 Disclosure required by court order.

(a) * * *

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under § 4.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

g. In Subpart F by adding the following new section to read as follows:

§ 4.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall be made available to the public only in accordance with this part and shall not be sold or rented. Unless disclosing the names and addresses would be prohibited as a clearly unwarranted invasion of personal privacy under § 4.63 or they are otherwise exempt from disclosure, they may be made available in accordance with the requirements of this part, including payment of fees for search and copying.

2. A new Part 7 is established as follows:

PART 7—PROTECTION OF PRIVACY

Subpart A—General Provisions

§ 7.1 Purpose and scope.

(a) This part establishes procedures to implement the Privacy Act of 1974 (5 U.S.C. 552a). It applies to records about individuals that are maintained, collected, used, or disclosed by the Food and Drug Administration and contained in Privacy Act Record Systems.

(b) This part does not:

(1) Apply to Food and Drug Administration record systems that are not Privacy Act Record Systems or made available to an individual records that may include references to him but that are not retrieved by his name or other personal identifier, whether or not contained in a Privacy Act Record System. Part 4 of this chapter (the public information regulations) and other regulations referred to therein determine when records are made available in such cases.

(2) Make any records available to persons other than (i) individuals who are the subjects of the records, (ii) persons accompanying such individuals under § 7.43, (iii) persons provided records pursuant to individual consent under § 7.72, or (iv) persons acting on behalf of such individuals as legal guardians under § 7.75. Part 4 of this chapter (the public information regulations) and other regulations referred to therein determine when records are made available to members of the public generally. Subpart G of this part limits the provisions of Part 4 of this chapter with respect to disclosure of records about individuals from Privacy Act Record Systems to persons other than individuals who are the subjects of the records.

(3) Make available information compiled by the Food and Drug Administration in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such information to any member of the public, including any subject individual or party to such litigation or proceeding shall be governed by applicable constitutional principles, rules of discovery, and Part 4 of this chapter (the public information regulations).

§ 7.3 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 deal-
PROPOSED RULES

§7.30 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 only by personal identifiers other than individual names, a system of records that 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 §7.30, ascertain the identity of individuals who are the subjects of the records.

(b) Personal identifiers includes individual names, identifying numbers, symbols, or other identifying designations assigned to individuals.

(c) "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 complaints.

(d) "Department" means Department of Health, Education, and Welfare.

§7.10 Policy concerning records about individuals.

Information about individuals in Food and Drug Administration records shall be collected, maintained, used, and disseminated in such a manner 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 health and welfare responsibilities of the agency, and administrative and program management needs.

Subpart B—Food and Drug Administration Privacy Act Record Systems

§7.20 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 §7.3(e) that is not covered by a notice published by the Department, the Civil Service Commission, 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.

Practices in the system (i.e., use outside the Department of Health, Education, and Welfare that is compatible with the purpose for which the records were collected) 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 include, history, what inferences may be drawn), 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) Whether any records in the system are exempt from access and contest under §7.61.

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

(10) Except to the extent that records in the system are exempt from access and contest under §7.61:

(I) The procedures whereby an individual can be notified at his request if the system of records contains a record about him.

(II) The procedures whereby an individual can be notified how access can be gained to any record about him contained in the system on suitable procedure for amendment or contest of its content.

§7.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the Fair Information Practices Staff in the Department, the Office of Management and Budget (Information Systems Division), and the Congress of any proposal to change or establish Privacy Act Record Systems that meet the criteria in paragraphs (b) and (c) of this section, in accordance with procedures of 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 §7.20(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 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 these 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

(c) A contract is considered to accomplish a Food and Drug Administration function if the program or activity its supports is principally operated by the contractor, or under the direct management of the Food and Drug Administration.

(1) Systems of records from which information is retrieved by individual or personal identifiers, that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(2) A contract is considered to accomplish Food and Drug Administration function if the program 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 or personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(3) A contract is not considered to accomplish a Food and Drug Administration function if the program or activity it supports is not principally operated on behalf of, or is not under the direct management of, the Food and Drug Administration. For example, this part does not apply to systems of records:

(1) Operated under contract with the Food and Drug Administration by State or local government agencies, or organizations representing such agencies, when such agencies or organizations are...
also performing State or local government functions.

(2) Operated by contractors with the Food and Drug Administration by individuals or groups of individuals whose function is delivery of health services, such as hospitals, physicians, pharmacists, and other health professionals, and that report information concerning products, e.g., injuries or product defects, to the Food and Drug Administration. Before such contractors submit information to the Food and Drug Administration, the names of the identifiers of patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted, unless the contract provides otherwise. If the Food and Drug Administration—subsequently needs the names of such individuals, a separate request will be made.

(3) Relating to individuals whom the contractor with whom the contractor otherwise deals, in the course of providing goods and services to the Food and Drug Administration.

(4) Operated under grants.

(d) The requirements of this part shall apply where who operate a system of records not subject to this part reports to the Food and Drug Administration information that is a system of records about individuals from which personal information is retrieved by names or other personal identifiers. Where the information would be a new Privacy Act Record System, or a change in an existing Privacy Act Record System of a type described in §7.21, the Food and Drug Administration shall comply with the requirements of §7.21.

(e) The Food and Drug Administration will review all contracts before award to determine whether operation of a system from which information is retrieved by individual names or other personal identifiers will be required of the contractors of the operators of the contract or as a matter of practical necessity. If such operation will be required, the solicitation and contract shall include the following clause, or a clause of similar effect: Whenever the contractor or any of his employees is required by this contract to operate a system of records from which information is retrieved by individual names or other personal identifiers in order to accomplish a Food and Drug Administration function, the contractor and every employee is considered to be an employee of the Food and Drug Administration and shall operate such system of records in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), regulations of the Food and Drug Administration in 21 CFR Part 7, and rules of conduct that apply to the contractor or any of his employees who work with such systems of records. The contractor and his employees are subject to the criminal penalties set forth in 5 U.S.C. 552a(i) for violations of the Privacy Act.

§7.31 Records stored by the General Services Administration and archival records.

(a) Food and Drug Administration records that are stored, processed, and serviced by the General Services Administration, the basis of informal procedures, rather than the procedures specified in §§7.40 through 7.43.

(b) In any case where the record is not disclosed to the individual the FDA Privacy Coordinator shall document in writing the reasons for requesting the individual to designate a representative and how the medical record was disclosed to the representative.

FEDERAL REGISTER, VOL. 40, NO. 167—WEDNESDAY, AUGUST 27, 1975
Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

§ 7.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record exists, request that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any FDA and Drug Administration Privacy Act Record System to the FDA Privacy Coordinator (HF-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

(c) Requests shall be in writing and shall name the Privacy Act Record System or Systems concerning which the individual requests notification of whether there are records about that are retrieved by reference to his name or other personal identifier. To help assure a prompt response, an individual should indicate that he is making a "Privacy Act" request on the request form and in a prominent manner in the letter.

(d) An individual who merely wishes to be notified whether a Privacy Act Record System contains a record about him ordinarily need not provide any verification of his identity other than his name. The mere fact that the Food and Drug Administration has a record about an individual in any of its Privacy Act Records would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where more disclosure of the fact that a record about the individual exists would be a clearly unwarranted invasion of personal privacy, further verification of the identity of the individual shall be required.

(e) An individual who requests that he be given access to a copy of records about him exists, should indicate whether he prefers (1) to have copies of any such records mailed to him in accordance with § 7.43(a)(1), which may involve a fee under § 7.45, including information to verify his identity under § 7.44 or (2) to use the procedures for access in person under § 7.43(a)(2).

(f) A request for notification and access may be submitted under this subpart concerning any Privacy Act Record System that is exempt under § 7.61, as indicated in the notice for the system. Where the system is exempt under § 7.61, and access to the requested record is not granted under § 7.65, the request shall be handled under the provisions of Part 4 of this chapter (the public information regulations).

(g) The Public Records and Documents Center shall maintain and make available copies of the forms (FD-________, Privacy Act Request forms) to assist individuals in filing requests under § 7.40.

§ 7.41 Processing of requests.

(a) An individual or his guardian under § 7.75 shall not be required to show any justification or need to obtain notification under § 7.42 or access to a record under § 7.63.

(b) Where it is unclear whether an individual seeking access to records about himself is making a request under this subpart, the FDA Privacy Coordinator or the Public Records and Document Center will consult with him in making an appropriate request under this subpart, or under the provisions of Part 4 of this chapter (the public information regulations), or both.

(c) Requests shall not be delivered to any point in the agency other than the FDA Privacy Coordinator (HF-50) shall be promptly redirected to this official. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request shall consult with the FDA Privacy Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request, the responsible official shall promptly make a record of the facts that a request has been received and the identity of the requestor.

(e) A letter in accordance with § 7.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration.

(1) An individual's access to records about himself that are retrieved by his name or other personal identifiers and contained in any Privacy Act Record System may only be denied by an Associate Commissioner of the Food and Drug Administration. An individual shall not be denied access to any record that is otherwise available to him under this part except on the grounds that it is exempt under § 7.61 and not required to be disclosed under § 7.65(a)(2) or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential, or includes information the disclosure of which would constitute a clearly unwarranted invasion of the personal privacy of another individual.

(f) The FDA Privacy Coordinator shall assure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under § 7.61. Records maintained under this subpart concerning any Privacy Act Record System shall not be considered to be Privacy Act Record Systems. All records required to be kept under this section shall be regarded as confidential and shall not be disclosed under Part 4 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

§ 7.42 Responses to requests.

(a) The FDA shall respond to an individual's request for notification as to whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal identifier by sending a letter under this paragraph.

(1) If there are no records about the individual that are retrieved by his name or other personal identifier in the named Privacy Act Record System, or the requester is not an "individual" under § 7.43(a), the letter shall so state. Where appropriate, the letter shall indicate that the Food and Drug Administration's public information regulations in Part 4 of this chapter prescribe general rules governing the availability of information to members of the public and that a request may be made in accordance with Part 4 of this chapter for records that are not retrieved by the requester's name or other personal identifier from a Privacy Act Record System.

(2) If there are records about the individual that are retrieved by his name or other personal identifier and the named Privacy Act Record System is not exempt from individual access and contest under § 7.61, or the system is exempt but access is allowed or required under § 7.65, the letter shall inform him that the records exist and shall include:

(i) Enclose a copy of the records under § 7.43(a)(1) or indicate that the records will be sent under separate cover, where there has been adequate verification of the identity of the individual under § 7.44 and the fees under § 7.45 do not exceed $25, or

(ii) Inform the individual of the procedures to obtain access to the records by mail or in person under § 7.43(a)(2), as well as the approximate dates by which the requested records can be provided (if the records are not then available), the location at which access will be had, and the information needed, if any, to verify the identity of the individual under § 7.44.

(3) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, and the system is exempt from individual access and contest under § 7.61 and access is not allowed or required under § 7.65, the letter shall inform him that the records are exempt from access and contest under the Privacy Act. If the system is not appropriate, the letter shall also indicate whether records will be available under Part 4 of this chapter (the public information regulations).

(4) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, but a final determination has not yet been made with respect to disclosure of all of the records covered by the request, e.g., because it is necessary to consult another person or agency having an interest in the confidentiality of the records, the
letter shall explain the circumstances and indicate when a final answer will be given.

(b) Access to a record may only be denied by an Associate Commissioner or his designate. If access to any record is denied, whether or not payment has yet been received as a result of a request for a copy of the records, 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 4 of this chapter (the public information regulations).

d) Any previous request for a record about himself, under this part or Part 4 of this chapter (the public information regulations), the Food and Drug Administration shall require prepayment 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 4 of this chapter.

§ 7.43 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 record in person between 8 a.m. and 4:30 p.m. at the office of the FDA Privacy Coordinator, at any Food and Drug Administration field office listed in § 2.7.3 of this chapter, or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangements for such review can be made by consultation between the FDA Privacy Coordinator and the individual seeking access to a record.

(b) A written request shall explain the circumstances of the request, the nature of the record sought, and the fees involved. Where the individual is not given a copy of the record to retain, no charge shall be made for the costs of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(c) The Food and Drug Administration will make every reasonable effort to ensure that record made available under this section is understandable by the individual, such as by providing an attachment explaining the records.

(d) Access to requested records shall be provided as promptly as possible.

§ 7.44 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 4 of this chapter (the public information regulations).

(b) An individual who appears in person at a specific location for access to records about himself shall verify his identity in one of the following ways:

(1) The individual shall provide his name, current address, and at least one piece of tangible identification such as driver's license, passport, alien or voter registration card. Identification information with current photographs are preferable but not required. If an individual has no identification but is personally known to the Food and Drug Administration employee, such employee shall make a written record verifying the subject individual's identity.

(2) Where the individual can provide no identification papers, he may be required to certify in writing that he is the individual who he claims to be and that he understands that the knowing and willful request for or release of records concerning an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(c) Under certain circumstances the identification provided under paragraph (b) of this section may not be sufficient. Such circumstances include but are not limited to:

(1) The sensitive nature of records to be disclosed such as medical records;

(2) The inability of the responsible Department official to distinguish between records of individuals with the same name or title;

(3) The apparent discrepancy between available information and the identity of the individual, such as when he appears to be much younger than the individual whose record is requested.

When any such circumstance exists, further confirmatory information shall be solicited from the individual. Only the minimum amount of information required to ensure that disclosure may lawfully be made will be collected. The information solicited shall parallel the information already contained in the records. Examples might be years of attendance at a particular educational institution, rank attained in the uniformed services, date and/or place of birth, names of parents, specific times treated for a particular medical condition, or an occupation. Where requests do not contain sufficient information to verify the identity of the Individual requesting the record, the Food and Drug Administration shall inform the requester in writing that no action can be taken without the submission of further information and inform the requester what further information may be necessary to process the request.

(d) When an individual makes a personal request for access to his record and is accompanied by another person, the Food and Drug Administration shall ask the individual for a signed statement authorizing disclosure of or discussion of personal records in the presence of such person.

(e) A parent of a minor child or legal guardian of a legally incompetent individual shall verify his own identity in the manner described in this section as well as his relationship to the Individual whose record is sought. A copy of the child's birth certificate or a court order shall be presented.

§ 7.45 Fees.

(a) When applicable, fees for copying records shall be made 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. No fee may be charged for making a search of the 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 person designated by the individual under § 7.32, no fee will be charged.

(b) The fee schedule is as follows:

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

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

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

(d) 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 Operations Branch, HFA-210, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Advance deposit shall be required where the total amount exceeds $50.

Any appeal filed in the Civil Service Commission regulations (5 CFR 297.115), no fee may be charged for the first copy of a personnel record, or portion thereof, provided to the subject individual.

Subpart E—Procedures for Requests for Amendment of Records

§ 7.50 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 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 request to that agency. The Food and Drug Administration shall proceed in accordance with § 7.51(d).

(3) Where another agency was the source of and has control of the record, refer the request to that agency.

(4) If an accounting was made under § 7.11(c) of a disclosure of the record under § 7.71(a), provide a copy of the record as amended to all previous recipients of the record as requested.

§ 7.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

1. Amend any portion of the record which the agency has determined, based upon a preponderance of the evidence, is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete, and, in accordance with paragraph (d) (3) of this section, inform the individual and previous recipients of the record that has been amended of the amendment.

2. Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Such refusal may only be issued by an Associate Commissioner of the Food and Drug Administration or his designate.

3. Where another agency was the source of and has control of the record, refer the request to that agency.

4. That the individual has a right to seek judicial review of the refusal to amend the record.

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

1. Of his decision and the reasons for it.

2. Of the individual's right to file a concurrence statement administratively or file a petition for judicial review. The Commissioner's decision not to amend the record as requested will be made available to all persons listed in an accounting as having previously received the record and to any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

4. That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with § 7.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

§ 7.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under § 7.51(b), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under § 7.70 or § 7.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be subject to a request for amendment under § 7.50.

(c) If an accounting was made under § 7.71(d) or of a disclosure of the record under § 7.71(a), provide a copy of the record as amended to all previous recipients of the record.

§ 7.52 Administrative appeals of refusals to amend records.

(a) If an individual disagrees with a refusal under § 7.51(a) (2) to amend a record, he may appeal that refusal to the Commissioner of Food and Drugs, Rm. 14-81, 5600 Fishers Lane, Rockville, MD 20852.

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

1. Of his decision and the reasons for it.

2. Of the individual's right to file a concurrence statement administratively or file a petition for judicial review. The Commissioner's decision not to amend the record as requested will be made available to all persons listed in an accounting as having previously received the record and to any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

4. That the individual has a right to seek judicial review of the refusal to amend the record.

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§ 7.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or updated by another agency, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its own record, and
(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under § 7.71(d) by the discloser under § 7.71(a), inform all previous recipients of the record about the amendment or provide to them the statement of disagreement and the agency providing any.

Subpart F—Exemptions

§ 7.60 Policy.

It is the policy of the Food and Drug Administration that the records systems should be exempted from the requirements of the Privacy Act only to the extent essential to the performance of law enforcement functions under laws administered and enforced by the Food and Drug Administration or that govern the agency.

§ 7.61 Exempt systems.

(a) Investigatory material compiled for law enforcement purposes, including criminal law enforcement purposes, in the Food and Drug Administration Privacy Act Records listed in paragraph (b) of this section is exempt from the following provisions of the Privacy Act (5 U.S.C. 552a) and of this part:

1. Such material is exempt from 5 U.S.C. 552a(c)(3) and § 7.71(a)(4), requiring that an individual be provided with the accounting of disclosures of records about himself from a Privacy Act Record System.

2. Except where access is required under 5 U.S.C. 552a(c)(2) and § 7.65(a)(2), such material is exempt from 5 U.S.C. 552a(d) (1) through (4) and (1) and (2) and § 7.40 through 7.54 requiring procedures for individuals to be given notification of and access to records about themselves in Privacy Act Record Systems and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such record.

3. Such material is exempt from 5 U.S.C. 552a(e)(4) (G) and (H) and § 7.30(b)(10) requiring inclusion in the notice for the system of information about agency procedures for notification, access, and contest.

4. Such material is exempt from 5 U.S.C. 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice for the Privacy Act Record System, and the consequences to the individual of not providing the information, but only with respect to information compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory material compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated for paragraph (a) of this section:

1. Clinical Investigator Records, HEW/FDA.

2. Regulated Industry Employee Enforcement Records, HEW/FDA.

3. Employee, consultant, and contractor security and investigative records that are the subject of a Department notice, to the extent that these files are maintained by the Food and Drug Administration.

(c) The system described in paragraph (b)(3) of this section includes investigatory material compiled solely for the purposes of regulating, controlling, or financing Federal civilian employment, military service, Federal contracts, and access to classified information. This material is exempt from disclosure under § 7.70 to the extent that the disclosure 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 after September 27, 1975.

The individual requesting the information will be given a reasonable opportunity to review and contest the material.

§ 7.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt under § 7.61, an individual entitled to request access under § 7.40 for notification concerning whether a system-about him exists and request access to any records about him contained therein that 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 under Part 4 of this chapter (the public information regulations) when the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§ 7.40 through 7.54; and

2. Shall be given access upon request to any records requested from a Privacy Act Record System.

(c) Records subject to Food and Drug Administration enforcement action under § 7.61 that concern an individual subject to 5 U.S.C. 552a(c)(2) and not to 5 U.S.C. 552a(c)(2) that have been used to deny the individual any right, benefit, or privilege which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. No record shall be disclosed 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.

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

§ 7.70 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 § 7.75;

2. To a third party pursuant to a written request by, or with the written consent of, the individual to whom the record pertains, or his legal guardian under § 7.75.

(b) To any person:

1. 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;

2. Where disclosure is required by Part 4 of this chapter (the public information regulations);

(c) Within the Department of Health, Education, and Welfare 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 paragraph, 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 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 that is subject to § 7.70.

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

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

(a) Except as provided in § 7.70, a report 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) For use, described as a "routine use" in the notice for the system under § 7.20(b) (6) that is compatible with the purpose for which the record was collected.

(2) To the Bureau of Census for a census, survey, or a related activity pursuant to Title 13 of the United States Code.

(3) To a recipient who has provided advance assurance, pursuant to paragraph (c) (2) of this section that the record will be used solely as a statistical research or reporting record and will not be communicated to the recipient to any other person except in a form that is not individually identifiable.

(4) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation, or to the General Services Administration for evaluation to determine whether the record has such value.

(5) To a Federal, State, or local agency for purposes of a law enforcement activity that is authorized by law, upon written request by the head of the agency specifying the particular portion of the record that is desired and the law enforcement purpose for which the record is sought. Disclosures under this paragraph are in addition to any disclosures for law enforcement purposes described as a "routine use" in a notice for a Privacy Act Record System.

(6) To a person pursuant to a showing of compelling circumstances affecting the health and safety of an individual, not necessarily the individual to whom the record pertains. Upon such showing, the Food and Drug Administration shall mail a notification of the fact of disclosure to the last known address of the individual who is the subject of the record.

(7) To either House of Congress, or to any Subcommittee or Committee thereof, to the extent that the subject matter of the record falls within its jurisdiction.

(8) To the General Accounting Office.

(9) Pursuant to an order of the court of competent jurisdiction. Upon such court-ordered disclosure, the Food and Drug Administration shall make reasonable efforts to notify the individual in accordance with § 4.68 (b) of this chapter.

(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 purpose and no further and that false pretexts shall be guilty of a misdemeanor and fined not more than $3,000. Such person may also be subject to prosecution under the False Reports to the Government Act, 18 U.S.C. 1001.

(d) An accounting shall be made, in accordance with paragraph (e) of this section, of any disclosure under paragraph (a) of this section of a record that is not a disclosure under § 7.70.

(e) Where an accounting is required under paragraph (d) of this section, the Food and Drug Administration shall:

(1) Record the name and address of the person or agency to whom the disclosure is made and the date, nature, and purpose of the disclosure. The accounting shall not be considered a Privacy Act Record System.

(2) Retain the accounting for 5 years or for the life of the record, whichever is longer, following the disclosure.

(3) Notify those recipients listed in the accounting of amendments or disputes concerning the records previously disclosed to them pursuant to §§ 7.51(d) (3), 7.53(e), or 7.54(c).

(4) Except when the record is exempt from individual access and contest under § 7.61 or to the extent that the accounting describes a transfer for a law enforcement purpose pursuant to paragraph (a) (6) of this section, make the accounting available to the individual to whom the record pertains, in accordance with procedures of Subpart D of this part.

(5) A single accounting may be used to cover disclosure(s) that consist of a continuing dialogue between two agencies over a prolonged period, such as discussion of an enforcement action between the Food and Drug Administration and the Department of Justice. In such cases, a general notation may be made that, as of a certain date, contact was initiated, to continue until resolution of the matter.

§ 7.72 Individual consent to disclosure of records to other persons.

(a) Individuals may consent to disclosure of their own personal information to other persons.

(b) In each case the consent shall be in writing and state specifically to whom the record may be released, or specific class such as providers of medical services, what information may be released, and for what purpose.

(c) An individual may consent to disclosure of his records to a specific person.

(d) An individual may consent to disclosure of his records to a specific person.

(e) An individual may request the Food and Drug Administration to transmit a specific record for submission to another person.

§ 7.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Federal purpose, timely, and complete before such record is disclosed under § 7.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under Part 4 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 7.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a record in a system of records, the individual shall be notified thereof under § 7.51 (a) (2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall inform the individual of the subsequent disclosure under this subpart and provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§ 7.75 Rights of legal guardians.

For the purposes of this part, the parent of any minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

Interested persons may, on or before September 26, 1975, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4–63, 5600 Fishers Lane, Rockville, Md. 20852, written comments regarding this proposal. Comments should be filed in quintuplicate (except that individuals may submit single copies), and should be identified with the Hearing Clerk dock number in brackets in the heading of this document. Received comments may be seen in the
above office. Monday through Friday, from 9 a.m. to 4 p.m., except on Federal holiday.

Dated: August 19, 1975.

SAM D. FRYE, Associate Commissioner for Compliance.

[FR Doc. 75-22413 Filed September 23, 1975.]

DEPARTMENT OF JUSTICE

PROPOSED RULES

[28 CFR Part 16]

[Order No. 619-75]

PROTECTION OF PRIVACY OF INDIVIDUAL RECORDS

Notice of Proposed Rulemaking

The Department of Justice proposes to issue regulations concerning the implementation of the Privacy Act of 1974, Pub. L. 93-579, including provisions for individuals to seek access to records pertaining to themselves contained in systems of records maintained by the Department of Justice which are retrieved by individual names or identifiers, except that for personnel records, where there is a conflict between these regulations and those of the Commission, the Civil Service Commission shall prevail. The regulations set forth the procedures by which individuals may seek access to records pertaining to themselves in these systems of records and request correction of them. The regulations also set forth the requirements applicable to Department of Justice employees maintaining, collecting, using or disseminating such records. These regulations are applicable to each Office, Division, Board, Bureau, Service and Administration of the Department (hereafter referred to as a "component").

The Assistant Attorney General for Administration shall provide that the provisions of this subpart and any regulations thereof shall be brought to the attention of and made available to:

(1) Each employee at the time of issuance of this subpart and any amendment thereto; and

(2) Each new employee at the time of employment.

(c) The Assistant Attorney General for Administration shall be responsible for assuring that employees of the Department of Justice are trained in the obligations imposed by the Privacy Act of 1974 and by these regulations, but each component of the Department is authorized to undertake training for its own employees.

§16.41 Access by individuals to records maintained about them.

(a) Access to available records. An individual seeking access to records about himself in a system of records, which have not been made available to the public pursuant to the Privacy Act of 1974, may present his request in person or in writing to the manager of the particular system of records to which he seeks access or to such other person as may be specified. System managers and others to whom requests may be presented are identified in the "Notice of Records Systems," published by the National Archives and Records Service, General Services Administration. Access to Department of Justice records maintained in National Archives and Records Service Centers may be obtained in accordance with the regulations issued by the General Services Administration. Access to records in multiple systems of records should be addressed to each component maintaining one of the systems. If a requester seeks guidance in defining his request, he may write to the Information Systems Staff, Office of Management and Finance, Department of Justice, 10th and Constitution Avenue, NW., Washington, D.C. 20530.

(b) Verification of identity. The following standards are applicable to any individual who requests records concerning himself, unless other provisions for identity verification are specified in the published notice pertaining to the particular system of records.

(1) An individual seeking access to records about himself in person may establish his identity by the presentation of a single document bearing a photograph (such as a passport or identification badge) or by the presentation of two items of identification which do not bear a photograph but do bear both a name and address (such as a driver's license, or credit card).

(2) An individual seeking access to records about himself by mail shall establish his identity by a signature, address, date of birth, place of birth, employee identification number if any, and one other identifier such as a photocopy of an identifying document.

(3) An individual seeking access to records about himself by mail or in persons cannot provide necessary documentation of identification may provide a notarized statement, swearing or affirming to his identity and to the fact that he understands the penalties for false statements pursuant to 18 U.S.C. 1001. Forms for such notarized statements may be obtained on request from the Information Systems Staff, Office of Management and Finance, U.S. Department of Justice, Washington, D.C. 20530.

(d) Accompanying persons. An individual seeking to review records about himself may be accompanied by another individual of his own choosing. Both the individual seeking access and the individual accompanying them shall be required to sign the required form indicating that the Department of Justice is authorized to discuss the contents of the subject record in the presence of both individuals.

(e) Specification of records sought. Requests for access to records, either in person or by mail shall describe the nature of the records sought, the approximate date covered by the record, the system or systems in which it is thought to be included as described in the "Notice of Records Systems," published by the General Services Administration. Access to the identity of the system manager or component of the Department having custody of the system of records. In addition, the published "Notice of Records Systems," for individual systems may include further requirements of specification where necessary to retrieve the individual record from the system.