erence herein, the procedural requirements imposed on the Joint Board by ERISA make the protections afforded by subsections (e) (4) (G) and (f) (1) unnecessary. For these reasons, the Joint Board seeks exemptions from the requirements of subsections (e) (4) (G) and (f) (1).

(5) Subsection (e) (1) of the Privacy Act of 1974 requires that the Joint Board maintain in its records only information that is relevant and necessary to accomplish a purpose of the Office required to be accomplished by statute or by executive order of the President. The Joint Board believes that imposition of said requirement would seriously impair its ability, and the abilities of its agents and other investigative entities to effectively investigate suspected or alleged violations of regulations and of civil or criminal laws. The Joint Board does not initiate inquiries into individuals' conduct unless it receives information evidencing violation by such individuals of the regulations governing performance of actuarial services with respect to plans to which ERISA applies. Sources of such information may be unfamiliar with the Joint Board's interpretations of said regulations and, therefore, may not always provide only relevant and necessary information. Therefore, it may often be impossible to determine whether or not information is relevant and necessary. For these reasons, the Joint Board seeks exemptions from the requirement of subsection (e) (1).

(6) Subsection (e) (4) (I) 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 imposition 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 cause sources to decline 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) (I).

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

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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 regulations to carry out the Privacy Act with respect to systems 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 or 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 request for amendment. 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 violations. The Food and Drug Administration's privacy regulations hereby proposed will comprise a new 21 CFR Part 7. The proposed regulations will apply to the systems of records that are listed in Privacy Act notices and are maintained by the Food and Drug Administration, except for official personnel records which shall be subject to Civil Service Commission regulations. These proposed regulations include procedures for individuals to learn whether they are the subjects of records in such Food and Drug Administration systems of records and to obtain access to and request amendment of these records. Certain systems of law enforcement records are proposed to be exempted from the procedures for individuals to be notified of records about themselves or to seek access or amendment. The proposed regulations would also restrict disclosures of records from systems of records subject to the Privacy Act. Conforming amendments are made to the Food and Drug Administration's public information regulations (21 CFR Part 4). The new regulations, with whatever revisions comments reveal to be appropriate, will become effective on September 27, 1975.

A separate notice elsewhere in this issue of the FEDERAL REGISTER describes Food and Drug Administration systems of records subject to the Privacy Act, other than those covered by the notice of the Civil Service Commission concerning certain personnel record systems and the notice of the Department of Health, Education, and Welfare concerning certain personnel and administrative management records.

GENERAL

1. The proposed regulations were developed in accordance with the guidelines issued by the Office of Management and Budget regarding Responsibilities for the Maintenance of Records About Individuals by Federal Agencies (OMB Circular No. A-108, hereinafter, "OMB Guidelines"), published in the FEDERAL REGISTER of July 9, 1975 (40 FR 28948). The OMB Guidelines are helpful in understanding the underlying policy, meaning, and effect of the proposed regulations. Provisions of the OMB Guidelines that are especially relevant to systems of records maintained by the Food and Drug Administration (hereinafter, "Privacy Act Record Systems") are cited herein.

2. It is the policy of the Food and Drug Administration to collect, use, and disclose records in a manner which protects individual privacy to the maximum extent practicable. This policy is stated in proposed § 7.10 of the regulations (21 CFR 7.10). The agency maintains few systems of records from which information is retrieved by individual name or other personal identifier, other than routine records for personnel or administrative management purposes. Most of the agency's records concern regulated products or establishments. The agency is interested in the activities of individuals only to the extent that these individuals are in some way involved in the development, production, or marketing of products it regulates.

RELATION TO PUBLIC INFORMATION LAW AND REGULATIONS

3. The public information regulations of the Food and Drug Administration at 21 CFR Part 4, published in the FEDERAL REGISTER of December 24, 1974 (39 FR 44602), implement the Freedom of Information Act (5 U.S.C. 552). The public information regulations contain several provisions designed to protect individual privacy.

Under § 4.21 of those regulations (21 CFR 4.21), it is recognized that an individual who is the subject of a Food and Drug Administration record may be provided a copy even if the record is not available for public disclosure because public disclosure would constitute an unwarranted invasion of that individual's personal privacy.

Section 4.63 of the regulations (21 CFR 4.63) lists instances in which disclosure of personnel, medical, and similar files constitutes a clearly unwarranted invasion of personal privacy. Under § 4.63 (a), names and other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project are required to be deleted before the record is available for public disclosure. Under § 4.63(b) persons who submit data concerning research to the agency are instructed that names and other information that would identify patients or research subjects should be deleted before submission to the agency. If the agency subsequently needs the names of such individuals a separate request will be made. Section 4.63(d) provides that the names of individuals conducting research shall not be deleted prior to disclosure unless extraordinary circumstances are shown. Under § 4.63(e), a request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless ac-

companied by the written consent of the named individual.

Where disclosure is sought of investigatory records compiled for law enforcement purposes under § 4.64 of the regulations (21 CFR 4.64), individuals who are the subject of FDA investigations generally have the same right to records about themselves as other members of the public. To protect personal privacy and prevent interference with enforcement proceedings, § 4.64(d) provides that the Commissioner will only rarely exercise his discretion to disclose records relating to possible criminal prosecution. During consideration of criminal prosecution, a similar rule applies under § 1.6 of the regulations (21 CFR 1.6) concerning presentation of views under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335). Where, after these investigations or hearings, a decision is made not to recommend criminal prosecution of an individual, the name of the individual shall be deleted from records prior to disclosure to other persons.

Section 4.82(b)(2) of the regulations (21 CFR 4.82(b)(2)) prohibits the Commissioner from making a discretionary disclosure of records that are exempt because the Food and Drug Administration finds that disclosure would constitute a clearly unwarranted invasion of personal privacy under § 4.63.

Under § 4.110 of the regulations (21 CFR 4.110), data and information about Food and Drug Administration employees is available as follows: The agency will disclose the name, title, grade, position description, salary, work address, and work telephone number of every employee, but not the home address and home telephone number. Also available are statistics on prior employment experience and subsequent employment experience of agency employees.

When a member of the public requests a copy of an adverse reaction report, product experience report, or consumer complaint, the Food and Drug Administration follows the policy that such records are available only after deletion of names and other information that would identify either the individual who is the subject of the report or the person making the report. This policy is reflected in 21 CFR 4.111, relating to data and information submitted voluntarily to the Food and Drug Administration; 21 CFR 8.9, relating to color additive petitions; 21 CFR 121.51, relating to food additive petitions; 21 CFR 514.11, relating to new animal drug applications; 21 CFR 514.10 relating to animal antibiotic drug applications; 21 CFR 312.5, relating to investigational human new drug notices; 21 CFR 314.14, relating to human new drug applications; 21 CFR 431.71, relating to human antibiotic drug records; 21 CFR 601.50, relating to records on licensed biologicals; and 21 CFR 730.7, relating to voluntary filings of cosmetic product experience.

If a person requests a copy of any adverse reaction report, product experience report, consumer complaint, or similar data and information, relating to a specific individual or specific incident, the request will be denied under § 4.111(c)(3)(vi) of the regulations (21 CFR 4.111(c)(3)(vi)) unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

4. It is important to understand the relationship between the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act of 1974 (5 U.S.C. 552a). The Privacy Act affects the Freedom of Information Act in several significant ways.

First, the Privacy Act gives special access rights to an individual who is the subject of a record contained in a system of records from which information is retrieved by reference to that individual's name or other identifying information pertaining to that individual (5 U.S.C. 552a (d) and (f)). No new rights of access to information are given by the Privacy Act to persons other than individuals who are the subject of records in such systems, those authorized to accompany them or to receive the records, or individuals' guardians.

Second, the Privacy Act restricts disclosure to third parties of records about individuals contained in Privacy Act Record Systems (5 U.S.C. 552a(b)). The Privacy Act restricts agency discretion to make disclosures of records about individuals in Privacy Act Record Systems, including disclosures to other Government agencies, where such disclosures are not required by the Freedom of Information Act. Thus, for example, an agency may no longer disclose a record the disclosure of which constitutes a clearly unwarranted invasion of personal privacy unless the subject individual consents to the disclosure, the disclosure is a routine use, or the Privacy Act otherwise specifically allows the disclosure.

Third, the Privacy Act provides that no exemption under the Freedom of Information Act shall be used to deny an individual access to a record about himself that is contained in a nonexempt Privacy Act Record System (5 U.S.C. 552 a(q)). Once the Privacy Act becomes effective, only Privacy Act exemptions, and provisions of law other than the Freedom of Information Act (such as 18 U.S.C. 1905 relating to trade secrets and confidential commercial information), may be used to deny an individual a record retrieved by his personal identifier and contained in a nonexempt Privacy Act Record System.

Finally, there are procedural differences between the two statutes with respect to special procedural rights given individuals who are the subjects of records in Privacy Act Record Systems, fees, time limits, and judicial review.

5. The regulations proposed in this notice include several amendments to the Food and Drug Administration's public information regulations in 21 CFR Part 4.

6. Section 4.20 of the regulations (21 CFR 4.20) is proposed to be amended to provide for an exception to the usual rule, under the public information regulations, that a person is not required to make any showing of justification or need to obtain disclosure of records. Under proposed paragraph (d) of § 4.20, a person may be required to supply the Food and Drug Administration with a statement of the purposes to which a requested record is to be put, and a certification that the record will be so used, when he is requesting discretionary disclosure of a record contained in a Privacy Act Record System about another individual. This conditional disclosure provision is to enable the Food and Drug Administration to determine whether it should exercise discretion under both the Freedom of Information Act (5 U.S.C. 552(b)) and the Privacy Act (5 U.S.C. 552a(b)(1), (3) through (11)) to disclose personal information not required to be publicly disclosed under the Freedom of Information Act. This provision also facilitates compliance with the Privacy Act requirement that an accounting be kept of the purpose of such discretionary disclosures (5 U.S.C. 552a (c)). New paragraph (d) of § 4.20 is most likely to be used when the Food and Drug Administration discloses to other agencies records containing personal information that are not required to be disclosed to the public generally, such as information provided other agencies for law enforcement purposes pursuant to a routine use in the system notice.

7. Several of the proposed amendments involve cross references to the proposed special requirements in 21 CFR Part 7 (the privacy regulations) for Privacy Act requests. Amendments are proposed to §§ 4.21 and 4.40 in the regulations (21 CFR 4.21 and 4.40), to clarify when requests by individuals for records about themselves shall be subject to the special requirements of Part 7. An individual's right to records about himself shall continue to be governed by 21 CFR Part 4 (the public information regulations) where (a) the record requested is not contained in a Privacy Act Record System; (b) the record is contained in a Privacy Act Record System but is not retrieved by the requester's name or other personal identifier; (c) the requester is not regarded as an individual under the Privacy Act (5 U.S.C. 552a(a)(2)); or (d) the system is exempt under proposed § 7.61 of the regulations (21 CFR 7.61).

The Food and Drug Administration recognizes that individuals often will not know whether a request should be submitted under the Freedom of Information Act or the Privacy Act. The agency will consult with individuals to help them to file appropriate requests, and will, where appropriate, consider requests by individuals for records about themselves to have been made both under 21 CFR Part 4 (the public information regulations) and 21 CFR Part 7 (the privacy regulations).

8. Subpart E of the public information regulations (21 CFR Part 4, Subpart E) setting forth limitations on exemptions is proposed to be amended in § 4.80 (21 CFR 4.80) to add a new paragraph (d)(1) providing that an individual request

covered by the Privacy Act shall be handled under the proposed privacy regulations (21 CFR Part 7), shall be denied only in conformity with the privacy regulations, and shall not be subject to exemptions in the public information regulations (21 CFR Part 4) that are founded solely on exemptions in the Freedom of Information Act (5 U.S.C. 552(b)). The new privacy regulations continue the prohibition against disclosure of information contained in statutes other than the Freedom of Information Act, such as 18 U.S.C. 1905 relating to protection of trade secrets and other confidential commercial information, and do not allow an individual to receive information that would invade the personal privacy of another individual.

Also, § 4.80 of the regulations (21 CFR 4.80) is proposed to be amended by adding a new paragraph (d)(2) indicating that the proposed privacy regulations (21 CFR Part 7, Subpart G) restrict certain disclosures of records contained in Privacy Act Record Systems to persons other than the subject individual. These restrictions go beyond those described in the public information regulations (21 CFR Part 4, Subparts D and E) and shall be controlling.

9. The public information regulations in § 4.82(b) (21 CFR 4.82(b)) are also proposed to be amended to implement the Privacy Act provision (5 U.S.C. 552a (b)) that permits public disclosure of a record contained in a Privacy Act Record System only where such disclosure is required by the Freedom of Information Act, has the subject's consent, is described as a routine use, or is otherwise specifically permitted by the Privacy Act. The effect of the Privacy Act on the Freedom of Information Act is to prohibit certain disclosures of personal information about individuals, without their consent, that would previously have been permissive—neither required to be disclosed nor required to be withheld. This indirect amendment of the Freedom of Information Act has a lesser impact on the Food and Drug Administration because § 4.82(b) of the agency's public information regulations already bars discretionary disclosure of records whose disclosure would constitute a clearly unwarranted invasion of personal privacy under § 4.63 of the regulations (21 CFR 4.63). However, the Privacy Act provision (5 U.S.C. 552a(b)(2)) may affect agency policy concerning discretionary disclosures under 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 intra-agency memoranda (5 U.S.C. 552(b)(5)) 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 § 4.82(b) (21 CFR 4.82(b)) to prohibit discretionary disclosure of personal records about individuals contained in Privacy Act Record Systems except in accordance with the new privacy regulations (21 CFR Part 7, Subpart G).

Consistent with the Privacy Act, the Food and Drug Administration will continue to adhere to its policy 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 individuals. Where all information 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 (21 CFR 4.83), relating to court-ordered disclosures of exempt records, is amended to include a new paragraph implementing the Privacy Act requirement (5 U.S.C. 552a(e)(8)) 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 process becomes a matter of public record." The requirement is construed as only being applicable to court-ordered disclosures of records about individuals that are not required to be disclosed under the Freedom of Information Act. The requirement will apply to all such records about individuals, whether or not a record is contained in a Privacy Act Record System, and is 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 this application of the 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) to implement the Privacy Act prohibition of sale or rental by an agency of an individual's name or address unless specifically authorized by law (5 U.S.C. 552a(n)). The act does not require the withholding of names and addresses otherwise permitted to be made public. Section 4.119 provides that names and addresses of individuals in Food and Drug Administration records shall only be made available in accordance with 21 CFR Part 4 (the public information regulations), i.e., such names and addresses shall be available unless disclosure is prohibited as a clearly unwarranted invasion of personal privacy under 21 CFR 4.63, or they are otherwise exempt from disclosure. Fees may be charged for search and copying of any name and address lists that are made available.

PROPOSED PRIVACY REGULATIONS

12. 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.

13. New § 7.1 (21 CFR 7.1) 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).

14. Proposed § 7.1 also includes a provision explaining that the Privacy Act does not make available information compiled by the Food and Drug Administration in reasonable anticipation of court litigation or administrative proceedings. This "no discovery" rule is based upon the legislative history of the act (Congressional Record of Nov. 21, 1974, p. H10955) and upon the provision in the act that "nothing in (section 552a) shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding" (5 U.S.C. 552a(d)(5)). The OMB Guidelines (40 FR 28960) explain that the "no discovery" rule of subsection (d)(5) is intended to apply whether the Government is the defendant or the plaintiff but is not normally available until the initiation of litigation or until an agency begins compiling information in reasonable anticipation of such litigation.

The fact that the statutory provision (subsection (d)(5)) only refers to civil actions or proceedings is not to be read as implying that the Privacy Act grants access to information compiled by the government in reasonable anticipation of criminal action or proceedings. From the legislative history of this provision in the Privacy Act, it is clear that government attorneys' work-product files, and related records compiled in anticipation of a lawsuit or other proceedings, are not subject to the Privacy Act in any circumstances. The purpose of subsection (d)(5) merely to confirm that those involved in litigation with the government can only obtain access to such records in accordance with the usual rules of discovery (Congressional Record, Nov. 21, 1974, p. H10955). Also, records sought by individuals who face prosecution or other action by the Government ordinarily would not be accessible to them pursuant to the law enforcement exemptions of the Privacy Act (5 U.S.C. 552a (j)(2) and (k)(2)). Individual access to Government records compiled in the course of civil and criminal proceedings will continue to be governed by constitutional principles, applicable rules of discovery, and 21 CFR Part 4 (the public information regulations).

RECORDS SYSTEMS SUBJECT TO THE PRIVACY ACT

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—

* * * * *

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

(3) * * *

(4) the term "record" means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and

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 finger 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 name of the individual or by some 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 28951–52).

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 28951), 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 activities with respect to regulated businesses (Senate Report 92–1183, p. 89).

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 OMB guidelines, which call for, 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 28951). 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 of regulated business enterprises, physicians and other health professionals engaged in clinical investigations or other essentially individual or personal 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, 40 FR 28951).

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. 552a(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 individually identifying 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 employee names for a purpose relating to overall accomplishment of agency mission, rather than for making determinations about the named individuals, are not records about individuals. Examples are in Food and Drug Administration's internal Program Oriented Data System, 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 expenditure of agency resources, use of employees' names as an index to locate laboratory notebooks concerning experiments or to identify product samples analyzed; internal work assignment systems identifying employees assigned to various tasks (e.g., inspections of certain establishments); and telephone directories giving name, title, organizational unit, room number, and telephone number. To the extent that any administrative management records are used to make determinations about individuals, or include personal information such as home address, they shall be regarded as personnel files subject to proposed § 7.32 of the regulations (21 CFR 7.32) and covered by the Department notice 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 specific subject (such as research done on a particular substance) are not records about individuals. Examples are information in card catalogs in Food and Drug Administration libraries; bibliographies appended to Food and Drug Administration documents; computerized information retrieval systems used to facilitate scientific review; or listings of cases litigated by the Food and Drug Administration.

d. Mailing lists and lists of individuals in an organization to be contacted or regulatory 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 rights, benefits, or privileges of individuals (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 the mere fact that a person is on the list would reveal personal information, which is not likely for any mailing or contact list that the Food and Drug Administration maintains. Proposed § 4.119 of the public information regulations (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 4.63) bars disclosures 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 28952), in determining whether a system of records is subject to the act it must be determined, first, whether there is built into the system a retrieval capability using individual names or personal identifiers and, second, whether the agency does, in fact, retrieve records about individuals by reference to names or personal identifiers. The Privacy Act does 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 filed by employee name. Individual name indexes are used sparingly. Most FDA records are retrieved by names or symbols of establishments or products, or by numbers of cases assigned by product sample num-

bers or chronologically by type of legal action. These establishment, product, or case records may include incidental references to an individual, but there is no way for information about an individual to be retrieved merely by reference to his name or other personal identifier without searching the records manually.

Where there is no retrieval capability and practice with respect to a requesting individual, the record system is not treated as a Privacy Act Record System. Requests for such records are subject to the Freedom of Information Act and 21 CFR Part 4 (the public information regulations). Although the agency could design a program to retrieve information from the system by reference to the individual's name, it would have no reason to do so since reference to files for establishments, products, or cases is generally sufficient for Food and Drug Administration purposes. The OMB Guidelines make clear that agencies should not develop new retrieval and indexing capabilities to serve individual needs for access under the Privacy Act (40 FR 28967), and that, indeed, development of elaborate cross references among records would increase the potential for privacy abuses (40 FR 28957).

Of course, individuals may request Food and Drug Administration records about themselves regardless of whether the record is filed or indexed by individual name or other personal identifier, and any records that exist may be made available under the public information regulations (21 CFR Part 4). In some instances, an individual may know that a file concerning a product or an establishment may contain information pertaining to him and he may ask for the information by naming the file, in which case such information will be disclosed in accordance with the public information regulations. The agency will help individuals to frame their requests so that they can obtain any available information about themselves contained in agency records, whether subject to the public information regulations (21 CFR Part 4) or the proposed privacy regulations (21 CFR Part 7).

Consumer complaints and correspondence are sometimes indexed by the name of complainants or correspondents to permit location of an earlier complaint or letter and related documents. Also, in some cases, individuals who are the subject of correspondence with other persons (e.g., the subject individual's legislative representative) may also appear in an index to this system. Any records so indexed by reference to the name of an individual will be treated as a Privacy Act Record System. Some regulatory records (e.g., establishment inspection reports) are in the general records files in headquarters and indexed by name of an individual, where the agency does not have an establishment file for the records. Records used for law enforcement, however, are subject to an exemption under proposed § 7.61 of the regulations (21 CFR 7.61).

The OMB Guidelines explain that the term "system of records" is intended to cover only records "under the control of the agency" (5 U.S.C. 552a(a)(5)) and not records kept by individual agency employees (40 FR 28952). Agency records are those intended for common access and enduring use, relied upon by the agency in supporting its actions, and subject to agency directives about maintenance, content, and use. "Uncirculated personal notes, papers and records which are retained or discarded at the author's discretion and over which the agency exercises no control or dominion (e.g., personal telephone lists) are not considered to be agency records within the meaning of the Privacy Act." However, no record maintained by an individual employee that is not an agency record may be used to make determinations about an individual.

19. In some instances, the Food and Drug Administration has a central records system (e.g., of correspondence) and agency offices that feed information into the central system also maintain copies of their submissions. Such an arrangement is regarded as a single Food and Drug Administration Privacy Act Record System. In other cases, another governmental body, such as the Civil Service Commisison or the Office of the Secretary, Department of Health, Education, and Welfare, requires and maintains a central records system, and the Food and Drug Administration maintains copies of records supplied to or kept in these systems. This, too, is regarded as a single system. For example, the Civil Service Commission maintains, and requires agencies to maintain, certain records about employees. The Privacy Act requirement of public notice of existence of a system of records subject to the act (5 U.S.C. 552a(e)(4)) is satisfied by publication by the agency requiring the records (in the example, the Civil Service Commission) of a single notice applicable to the entire records system. As another example, the Department of Health, Education, and Welfare is publishing a notice concerning the Department's payroll and related records, and it is thus unnecessary for the Food and Drug Administration to have published any notice concerning information in its files that are part of this system.

In proposed § 7.32 (21 CFR 7.32) and in the notice of the Food and Drug Administration's Privacy Act Record Systems, published elsewhere in this issue of the FEDERAL REGISTER, individuals are instructed to consult systems notices of the Civil Service Commission and the Department of Health, Education, and Welfare for reference to other record systems maintained, in part, by the Food and Drug Administration.

21. The definition of "personnel records" in proposed § 7.3(e) of the regulations (21 CFR 7.3(e)) would include any records about Food and Drug Administration employees (including part-time and special government employees) that contain personal information or are used ot make determinations about individuals.

There are some administrative management systems that are used in part for impersonal management information purposes, such as keeping track of a unit's total expenditures for training, 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 B 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) proposes 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 a contractor acts as custodian of the records (5 U.S.C. 552a(a)(5)). The act also specifically provides that "when an agency provides by 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) to be applied to such system" (5 U.S.C. 552a(m)). The OMB Guidelines (40 FR 28975–76) 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 ac-

tivities that are State and local activities as well as Federal ones, such as enforcement of food and drug laws, are not subject to the Privacy Act. Nor are injury or product defect reports provided to the Food and Drug Administration under contract with providers of health services. Contracts for consumer surveys or product registries may be subject to proposed 21 CFR Part 7, but only if personal information is retrieved by individual name or other personal identifier.

25. Under proposed § 7.32 of the regulations (21 CFR 7.32), official personnel records maintained in personnel offices are subject to the Civil Service Commission privacy regulations (5 CFR Parts 293 and 297), while other personnel records are subject to the proposed Food and Drug Administration privacy regulations (21 CFR Part 7). Access to records maintained in the unit in which an employee works may be granted without requiring observance of the formal requirements provision in these proposed regulations.

26. Proposed § 7.33 of the regulations (21 CFR 7.33), specifying special procedures for individual access to medical records, is authorized by the Privacy Act (5 U.S.C. 552a(f)(3)) and adapted from 45 CFR 5b.5(c) of the Department's proposed regulations, published in the FEDERAL REGISTER of August 14, 1975 (40 FR 34129). Under the act, medical records expressly include psychological records. Medical records would also include summaries prepared by Food and Drug Administration employees of conversations with physicians and other practitioners relating to the health of an individual.

Because few Food and Drug Administration Privacy Act Record Systems include medical records, it is expected that the proposed special procedures for medical records will rarely be used. The most common use would involve personnel records, and it is expected that medical records will generally be made available to the individual. The availability to an individual, or to other persons, of medical records about him that are not contained in Privacy Act Record Systems, such as drug adverse reaction reports, which are generally indexed by product name rather than individual name, would continue to be governed by the public information regulations (21 CFR Part 4).

PROCEDURES FOR ACCESS TO RECORDS

27. Proposed Subpart D of the regulations (21 CFR Part 7, Subpart D) prescribes procedures for an individual to discover whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal identifier and, if it does, to obtain access to the records, unless an exemption under proposed Subpart F of CFR Part 7 applies. Subpart D specifies procedures to be followed by individuals in filing requests and by FDA employees in responding to such requests. Procedures for verification of individual identity and a schedule of fees to be charged for copies of records are included. Proposed Subpart D implements 5 U.S.C. 552a(d)(1) and (f)(1), (2), (3), and (5).

PROCEDURES FOR REQUESTS FOR AMENDMENT

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-legislative administrative proceedings (OMB Guidelines, 40 FR 28958). Such records could be corrected only through established procedures consistent with the adversary process. Nor was the Privacy Act intended to permit collateral attack upon determinations already reached in judicial or quasi-judicial proceedings. Thus, an individual may not invoke the Privacy Act to challenge a conviction for a criminal offense or 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, and completeness of records will be similar to issues that can be, 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(b)(2)) the Food and Drug Administration may defer its final decision on a request to amend the record until completion of the proceedings to resolve the underlying claim if such proceedings provide a suitable forum for resolving the issue concerning the records. The Privacy Act does not require the establishment of new mechanisms for assessing the accuracy of its records or for reconciling disputes where such capabilities exist and do, or can be modified to, conform to the Privacy Act (OMB Guidelines, 40 FR 28968). This procedure is most likely to be used in personnel actions. For example, if an issue in an adverse personnel action is whether an employee's work is satisfactory, and the accuracy of a memorandum that is critical of the employee's work will be considered in the adverse personnel action proceeding, the agency's final response to a request under the privacy procedures for amendment of the memorandum shall be deferred pending resolution of the related issue in the adverse personnel action proceeding.

EXEMPTIONS

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 and character of the system of records (5 U.S.C. 552a(e)(4)), the restriction upon maintenance of records concerning the exercise by individuals of First Amendment rights (5 U.S.C. 552a(e)(7)), the restrictions upon disclosures of records from systems (5 U.S.C. 552a(b)), and the requirement that an accounting be kept of certain disclosures (5 U.S.C. 522a(c)). The Privacy Act recognizes, however, that the application of all of its requirements to certain categories of records would seriously and improperly hamper agency functions. The act therefore provides certain "general exemptions" (5 U.S.C. 522a(j)) and certain "specific exemptions" (5 U.S..C 522a(k)) from certain of its provisions. Systems of records exempted under a general exemption are subject to fewer requirements of the act than those exempted under a specific exemption. Before any system of records is exempt from any provisions of the Privacy Act, a regulation must be promulgated based upon a determination that the system falls within one of the categories that may be exempted and indicating the specific provisions from which the system is proposed to be exempted, with an explanation why the agency considers the exemption necessary.

The Privacy Act authorizes a general exemption (subsection (j)(2)) for any system of records that is:

> • • • maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities, and which consists of (A) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (C) 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 (j)(2)." Pursuant to a proviso in this exemption, individual access to investigatory material in such a system is not completely barred:

> • • • if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be eligible, as a result of the maintenance of such material, such material shall be provided to such individual except to the extent that the 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 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 the 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 (subsections (k)(2) and (k)(5)), systems of records can be exempted from the following subsections of the act: (c)(3), which requires agencies to make available to an individual the accounting of disclosures of a record about him; (d) which requires agencies to grant an individual access to a record about him upon request, permit him to seek amendments, provide for review, and note disputed matters; (e)(1), which requires agencies to maintain in their records only information on individuals that is relevant and necessary to accomplish an authorized purpose; (e)(4) (G), (H), and (I), which require that agencies publish notice of procedures for an individual to be notified of the existence of a record about him and for access and requests for amendment, and the sources of the record; and (f), which requires agencies to promulgate rules establishing procedures for notification, access, and requests for amendment.

Under the general law enforcement exemption (subsection (j)(2)), but not under the specific law enforcement exemption (subsection (k)(2)), systems of records can also be exempted from at least the following subsections of the act: (e)(2), which requires that information be collected directly from the subject individual to the greatest extent practicable; (e)(3), which requires that an individual be informed of the authority and purposes for collecting information, the routine uses, and the effects of not providing the information; (e)(5), which requires that records be maintained so as to assure fairness in determinations about individuals; (e)(8), which requires that notice be served of court-ordered disclosures of records; and (g), which provides civil remedies for violations of the act.

31. The Food and Drug Administration qualifies both for the general law enforcement exemption (subsection (j)(2)) and, to the extent that such exemption is inapplicable to any material, to the specific law enforcement exemption (subsection (k)(2)). The Food and Drug Administration's principal activity is enforcement of the Federal Food, Drug, and Cosmetic Act, which prescribes as criminal penalties both fines and imprisonment. Almost all violations of the act are subject to criminal prosecution. Enforcement of the act is accomplished through criminal prosecution as well as criminal and administrative proceedings, and the effectiveness of the latter remedies depends significantly upon the existence of the alternative of criminal prosecution. 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 purposes. 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 under statutes that the agency administers and enforces (such as the Federal Food, Drug, and Cosmetic Act and parts of the Public Health Service Act) or that govern the agency (such as general statutes relating to false reports to the government, conspiracy, perjury, bribery, conflict of interest, etc.). The Food and Drug Administration is thus not seeking to exempt record systems from the Privacy Act except 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 Commissioner has also examined 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, consultant, and contractor security and investigative records, which are part of a Department-wide system.

The exemption is based on both the general exemption provision for criminal law enforcement records (subsection (j)(2)) and, to the extent that the general exemption provision is inapplicable to any material, to the specific exemption provision for other law enforment records (subsection (k)(2)) of the Privacy Act (5 U.S.C. 552a). The exemption for certain records in the Food and Drug Administration, employee, consultant, and contractor security and investigative files is also based on subsection (k)(5) of the act in order to protect confidential sources in investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, and to classified information.

Investigatory material in these three systems is exempt from the following provisions of the Privacy Act and corresponding provisions of the proposed regulations:

(1) 5 U.S.C. 552a(c)(3), requiring that an individual be provided with the accounting of certain disclosures of records about himself from a Privacy Act Record System.

(2) 5 U.S.C. 552a(d) (1) through (4), (e)(4) (G) and (H), and (f), requiring 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 the record through procedures specified in regulations and system notices.

(3) 5 U.S.C. 552a(e)(3), requiring that individuals asked to supply information be provided a statement of the authority and purpose for requesting the information, its routine uses, and the consequences of not providing the information.

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 otherwise required by 5 U.S.C. 552a(e)(3).

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 bases for action. The identity of confidential sources, the lives of investigators, and investigative 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 law 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:

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

35. The Food and Drug Administration is not proposing to take advantage of the full scope of the exemptions for law enforcement record 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 essential 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 information, such as educational credentials, provided to another agency or an institution.

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 the name of 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 Records, the Food and Drug Administration will determine the regulatory status of the requester to determine whether the requester is a sole proprietor or another person not regarded as "individual" for purposes of the Privacy Act. If the requester is an "individual" (whether or not potentially subject to FDA enforcement action as an employee of a regulated enterprise), 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 prohibited from disclosure under 18 U.S.C. 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 such material would be exempt only under the specific law enforcement exemption provision of the act (5 U.S.C. 552a(k)(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 restrict disclosures of records contained in Food and Drug Administration Privacy Act Record Systems, implementing 5 U.S.C. 552a(b). The subpart would also require, in proposed § 7.71, which implements 5 U.S.C. 552a(c), 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 5 U.S.C. 552a(e)(6)), under proposed § 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, or 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 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.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040, et seq., as amended 21 U.S.C. 321 et seq.); the Public Health Service Act (sec. 1 et seq., 58 Stat. 682, as amended; 42 U.S.C. 201 et seq.); the Freedom of Information Act (Pub. L. 90-23, 81 Stat. 54-56, as amended; 5 U.S.C. 552); the Privacy Act of 1974 (Pub. L. 93-579, sec. 2 et seq., 88 Stat. 1896, 5 U.S.C. 552a), and all other statutory authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

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 paragraph (d) 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) Under § 7.71 of 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 requested 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 retrieved 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 retrieved 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), and not to the provisions of this subpart, if the record requested is retrieved 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.

(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, § 4.80 is amended by adding a new paragraph (d) to read as follows:

§ 4.80 Applicability of limitations on exemptions.

* * * * *

(d) In the case of a record in a Privacy Act Record System, as defined in § 7.3(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 (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in Part 7, Subpart G, of this chapter.

e. In Subpart E, § 4.82 is amended by adding a new paragraph (b)(4) to read as follows:

§ 4.82 Discretionary disclosure by the Commissioner.

* * * * *

(b) * * *

(4) 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. 552a(b), 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 Procedures

Sec.
7.1 Purpose and scope.
7.3 Definitions.
7.10 Policy concerning records about individuals.

Subpart B—Food and Drug Administration Privacy Act Record Systems

7.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.
7.21 Changes in systems and new systems.

Subpart C—Requirements for Specific Categories of Records

7.30 Records of contractors.
7.31 Records stored by the General Services Administration and archival records.
7.32 Personnel records.
7.33 Medical records.

Subpart D—Procedures for Notification and Access to Records in Privacy Act Record Systems

7.40 Procedures for submitting requests for notification and access.
7.41 Processing of requests.
7.42 Responses to requests.
7.43 Access to requested records.
7.44 Verification of identity.
7.45 Fees.

Subpart E—Procedure for Requests for Amendment of Records

7.50 Procedures for submitting requests for amendment of records.
7.51 Responses to requests for amendment of records.
7.52 Administrative appeals of refusals to amend records.
7.53 Notation and disclosure of disputed records.
7.54 Amended or disputed records received from other agencies.

Subpart F—Exempt Systems

7.60 Policy.
7.61 Exempt systems.
7.65 Access to records in exempt systems.

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.
7.71 Disclosure of records in Privacy Act Record Systems; accounting required.
7.72 Individual consent to disclosure of records to other persons.
7.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.
7.74 Providing notice that a record is disputed.
7.75 Rights of legal guardians.

AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 et seq., as amended (42 U.S.C. 201 et seq.); Pub. L. 90-23, 81 Stat. 54-56, as amended (5 U.S.C. 552); Pub. L. 93-579, 88 Stat. 1896 (5 U.S.C. 552a).

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 make 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 Food and Drug Administration records are disclosable to members of the public generally. Subpart G of this part limits the provisions of Part 4 of this chapter with respect to disclosures 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-

ings. Any such business enterprise that is identified by the name of one or more individuals is not an individual within the meaning of this part. Employees of regulated business enterprises are considered individuals. Accordingly, physicians and other health professionals who are engaged in business as proprietors of establishments regulated by the Food and Drug Administration are not considered individuals; however, physicians and other health professionals who are engaged in clinical investigations, employed by regulated enterprises, or the subjects of records concerning their own health, e.g., exposure to excessive radiation, are considered individuals. Food and Drug Administration employees, consultants, and advisory committee members, State and local officials, and consumers are considered individuals.

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

(c) "Privacy Act Record System" means a system of records about individuals under the control of the Food and Drug Administration from which information is retrieved by individual names or other personal identifiers. Where records are retrieved only by personal identifiers other than individual names, a system of records is not a Privacy Act Record System if the Food and Drug Administration cannot, by reference to information under its control, or by reference to records of contractors that are subject to this part under § 7.30, ascertain the identity of individuals who are the subjects of the records.

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

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

(f) "Department" means Department of Health, 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 so as to protect the right to privacy of the individual to the fullest possible extent consistent with laws relating to disclosure of information to the general public, the law enforcement responsibilities of the agency, and administrative and program management needs.

Subpart B—Food and Drug Administration Privacy Act Record Systems

§ 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(c) 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 contained 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 are made of the records), access controls, retention, and disposal of the records in that system.

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

(8) 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 of records, and the 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 of 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 those records, such as the combining of two or more existing systems;

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

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

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and § 7.20(b).

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

Subpart C—Requirements for Specific Categories of Records

§ 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 by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in § 7.71 or for maintenance of a system of records without notice as required in § 7.20.

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

(c) 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 organizations whose primary 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 and other personal 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 employs, or 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 when a contractor who operates 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 contractor, by the terms 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 Food and Drug Administration 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 in accordance with 44 U.S.C. 3103 shall be considered to be maintained by the Food and Drug Administration. The General Services Administration shall not disclose the record except to authorized Food and Drug Administration employees.

(b) Each Food and Drug Administration record pertaining to an identifiable individual that was transferred to the National Archives of the United States as a record determined by the National Archives to have sufficient historical or other value to warrant its continued preservation shall be considered to be maintained by the National Archives and shall not be subject to the provisions of this part.

§ 7.32 Personnel records.

(a) Present and former Food and Drug Administration employees desiring access to personnel records about themselves should consult system notices applicable to the agency's personnel records that are published by the Civil Service Commission and the Department as well as any notice issued by the Food and Drug Administration.

(b) The procedures of the Civil Service Commission at 5 CFR Parts 293 and 297 govern systems of personnel records about Food and Drug Administration employees that:

(1) The Commission maintains.

(2) Are maintained by the Division of Personnel Management, Food and Drug Administration, concerning headquarters employees.

(3) Are maintained by Department Regional Offices, concerning field employees.

These procedures may, if necessary, be supplemented in the Food and Drug Administration Staff Manual Guide. Current Food and Drug Administration employees should mail or deliver written requests for access to personnel records subject to this paragraph to the Director, Division of Personnel Management (HFA-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, or the personnel officer in the servicing Regional Personnel Office. Alternatively, an employee may direct the request to the FDA Privacy Coordinator (HF-50). Requests for access to personnel records of former employees that are located in Federal records centers should be directed to the Director, Bureau of Manpower Information Systems, U.S. Civil Service Commission, 1900 E St. NW., Washington, DC 20415. Requests for amendment of personnel records should be directed to these same officials.

(c) Any other Privacy Act Record Systems that contains personnel records, or records that otherwise concern agency employees, that are maintained by the Food and Drug Administration and are not described in paragraph (b) of this section, are subject to the provisions of this part. An employee shall be given access to records about himself that are maintained in the unit in which he works in response to an oral request and on the basis of informal procedures, rather than the procedures specified in §§ 7.40 through 7.43.

(d) With respect to any personnel records or records which otherwise concern agency employees and that are maintained by the Food and Drug Administration, whether such records are subject to paragraph (b) or (c) of this section:

(1) Refusal to grant access to a record, or refusal to amend a record upon request of an employee, shall only be made by the Associate Commissioner for Administration.

(2) Appeals of refusals under paragraph (d)(1) of this section may be made to the Commissioner of Food and Drugs where the records are maintained by the Food and Drug Administration.

§ 7.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The following procedures shall govern the disclosures of medical records to an individual:

(1) The FDA Privacy Coordinator may consult with a medical officer to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be disclosed to him. If it is determined that disclosure might have an adverse effect on the individual, he shall be requested, to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, a member of the individual's family, a member of the clergy, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) If no medical officer is available, the FDA Privacy Coordinator shall determine whether the disclosure to the individual is likely to have an adverse effect on him. If the FDA Privacy Coordinator determines that disclosure will not be likely to have an adverse effect on the individual, he shall disclose the record to the individual. If the FDA Privacy Coordinator determines that disclosure might have an adverse effect on the individual, or if he does not believe himself qualified to make such a determination, the individual shall be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a medical practitioner, a member of the individual's family, a member of the clergy, or other person who would be willing to review the record and discuss it with the individual.

(3) 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.

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 about him 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 Food 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 him 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 envelope 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 Systems would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where mere 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 himself, if any exist, 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 records 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 § 7.43.

(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 and aid 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 mailed or 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 should 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 fact that a request has been received and the date.

(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.

(f) 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.

(g) 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 the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individual's names or personal identifiers for so long as request for notification, access, or amendment is pending. The identity of individuals making requests under this subpart 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 § 7.3(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 either:

(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 locations at which access in person may 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 should inform him that the records are exempted from access and contest by § 7.61. Where appropriate, the letter shall also indicate whether the records are 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, wholly or in substantial part, 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) before the records are made available. If the fee is less than $50, prepayment shall not be required 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 § 2.175 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. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. 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.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood 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 papers with current photographs are preferable but not required. If an individual has no identification but is personally known to a 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 or acquisition of records concerning an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(3) Under certain circumstances the identification provided under paragraph (b) (1) or (2) of this section may not be sufficient. Such circumstances include but are not limited to:

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

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

(iii) 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 solicited. 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.

(c) Where an individual is seeking to obtain information about himself which may be retrieved by a name or identifier different from his current name or identifier (e.g., an alias), he shall be required to produce evidence, similar to that required in paragraph (b) of this section, to verify that he is the person whose record he seeks.

(d) A written request by mail shall contain the full name, current address, and signature of the individual. It shall also include a minimum of one piece of information which the appropriate notice indicates should be in the system to distinguish the requester's records from those of other individuals. Examples might be years of attendance at a particular education institution, rank attained in the uniformed services, date and 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 and receipt of further information and inform the requester what further information may be necessary to process the request.

(e) 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.

(f) 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) Where 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 § 7.33, no fee will be charged.

(b) The fee schedule is as follows:

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

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

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

(c) 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.

(d) As provided 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 records 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 that 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 individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Coordinator in accordance with § 7.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity must be provided as specified in § 7.44.

(d) Written acknowledgement of the receipt of a request to amend a record shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

§ 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.

(b) The agency may, for good cause, extend the period for taking action an additional 30 days if notice is provided to the individual explaining the circumstances of the delay.

(c) In reviewing a record to determine how to respond to a request to amend it, the Associate Commissioner, and the Commissioner shall assess its accuracy, relevance to a Food and Drug Administration purpose, timeliness, or completeness. The determination shall be made in the light of the purpose for which the records or system is used, the agency's need for the record, and the possible adverse consequences to the individual from the record if not amended. Whenever the Food and Drug Administration receives a request for deletion of a record, or portions of a record, it shall consider anew whether the contested information in the record is relevant and necessary to a Food and Drug Administration purpose.

(d) If the Food and Drug Administration agrees with an individual's request, it shall take the following actions:

(1) So inform the individual in writing.

(2) In accordance with statute, regulation, or procedure, amend the record to make it accurate, relevant to a Food and Drug Administration purpose, timely, or complete, making note of the date and fact of the amendment.

(3) If an accounting was made under § 7.71(d) 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 with the Food and Drug Administration a concise statement of the individual's reasons for disagreeing with the agency's decision not to amend the record as requested.

(3) That the statement of disagreement will be made available to all persons listed in an accounting as having previously received the record and 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 § 7.52(b)(2), 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) and (e) of a disclosure of the record under § 7.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.

§ 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 is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the 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) and (e) of the disclosure of the record 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 statement, if any.

Subpart F—Exemptions

§ 7.60 Policy.

It is the policy of the Food and Drug Administration that record systems should be exempted from the Privacy Act only to the extent essential to the performance of law enforcement functions under the laws that are 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 Record Systems 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(e)(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(k)(2) and § 7.65 (a)(2), (such material is exempt from 5 U.S.C. 552a (d) (1) through (4) and (f) 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 § 7.20(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 in 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 purpose of determining suitability, eligibility, or qualification for Federal civilian employment, military service, Federal contracts, and access to classified information. This material is exempt from disclosure under 5 U.S.C. 552a(k)(5) 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 that would reveal a confidential source must be advised in a general way that there exists an item of information in the record that would reveal a confidential source.

§ 7.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt under § 7.61, an individual may nevertheless make a request under § 7.40 for notification concerning whether a system about him exists and request access to any records about himself 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) or 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 that is subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) that have been used to deny the individual any right, benefit, or privilege to 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. The individual requesting the information that would reveal a confidential source must be advised in a general way that there exists an item of information in the record which would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under § 4.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under § 7.61.

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.

(3) To any person:

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

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

(4) 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 section, officers or employees of the Department shall include the following categories of individuals, who shall thereafter be subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee: Food and Drug Administration consultants and advisory committees, State and local government employees for use only in their work with the Food and Drug Administration, and contractors and their employees to the extent that the records of such contractors are subject to the requirements of this part under § 7.30.

(b) 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 record about an individual that is contained in a Privacy Act Record System shall not be disclosed by any method of communication except under any of the

following circumstances, which are subject to the limitations of paragraphs (b) and (c) of this section and to the accounting requirement of paragraph (d) of this section:

(1) For a use, described as a "routine use" in the notice for the system under § 7.20(b)(5) 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 by 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 disclosure, 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 § 4.83(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 purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

Under 5 U.S.C. 552a(i)(3), any person who knowingly or willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000. 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(c), 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 acounting available to the individual to whom the record pertains, in accordance with procedures of Subpart D of this part.

(f) 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 records about themselves to other persons in several ways, for example:

(1) An individual may give consent at the time that the information is collected for disclosure for specific purposes or to specific persons.

(2) An individual may give consent for disclosure of his records to a specific person.

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

(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, if applicable, for what time period. A blanket consent to release all information to unspecified persons will not be honored. Verification of the identity of the individual and, where applicable, of the person to whom the record is to be released shall be made in accordance with § 7.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in § 7.71(e)(2).

§ 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 Food and Drug Administration 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 refusal to amend a record 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 in any subsequent disclosure under this subpart 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. 4-65, 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 docket number found 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 legal holidays.

Dated: August 19, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-22413 Filed 8-26-75;8:45 am]

DEPARTMENT OF JUSTICE

[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 them contained in systems of records and to seek correction of those records. The proposed regulations also set forth the obligations of the Department to insure the security, accuracy and completeness of records it maintains and to insure employee compliance with the Privacy Act of 1974.

Persons wishing to comment on the proposed regulations may address their comments in writing to:

Assistant Attorney General, Office of Legal Counsel, U.S. Department of Justice, Washington, D.C. 20530.

All comments must be received on or before September 8, 1975.

No oral hearings are contemplated.

By virtue of the authority vested in me by 5 U.S.C. 552a and as Attorney General of the United States, Part 16 of Title 28, Code of Federal Regulations, is hereby amended by adding thereto a new Subpart D as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

Subpart D—Protection of Privacy of Individual Records

Sec.

Subpart D—Protection of Privacy of Individual Records

§ 16.40 Purpose and scope.

(a) This subpart contains the regulations of the Department of Justice implementing the Privacy Act of 1974. Pub. L. 93-579. The regulations apply to all records contained in systems of records maintained by the Department of Justice which are retrieved by individual name or identifier, except that for personnel records, where there is a conflict between these regulations and those of the Commission, Civil Service Commission regulations 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").

(b) The Assistant Attorney General for Administration shall provide that the provisions of this subpart and any revisions 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 insuring 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 exempted from access 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 person who cannot provide the 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.

(c) *Verification of guardianship.* The parent or guardian of a minor or a person judicially determined to be incompetent and seeking to act on behalf of such minor or incompetent shall, in addition to establishing his own identity, establish the identity of the minor or other person he represents as required in paragraph (b) of this section and establish his own parentage or guardianship of the subject of the record by furnishing either a copy of a birth certificate showing parentage or a court order establishing the guardianship.

(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 him 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 dates covered by the record, the system or systems in which it is thought to be included as described in the "Notices of Records Systems" published by the General Services Administration, and the identity of the system manager or component of the Department having custody of the system of records. In addition, the published "Notice of Systems Records" for individual systems may include further requirements of specification where necessary to retrieve the individual record from the system.