section 510 (a)–(j) of the act shall be subject only to the special disclosure provisions established in §§ 207.37 and 807.37 of this chapter.

[42 FR 42526, Aug. 23, 1977]

§ 20.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration's Freedom of Information Public Room:

(1) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date the approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

(2) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as is specified in paragraph (a)(1) of this section except that it does not show a withdrawal date.

(3) A listing of new drug applications, abbreviated new drug applications, which were approved since 1938 and which are still approved, covering marketed prescription drug products except prescription drug products covered by applications deemed approved under the Drug Amendments of 1962 and not yet determined to be effective in the Drug Efficacy Study Implementation program. The listing includes the name of the active ingredient, the type of dosage form, the route of administration, the trade name of the product, the name of the application holder, and the strength or potency of the product. The listing also includes, for each active ingredient in a particular dosage form for which there is more than one approved application, an evaluation of the therapeutic equivalence of the drug products covered by such applications.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 20.61, 312.130, and 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 45 FR 72608, Oct. 31, 1980; 46 FR 8457, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

§ 20.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 20.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall not be sold or rented. Names and addresses shall not be disclosed if disclosure is prohibited as a clearly unwarranted invasion of personal privacy, e.g., lists of names and home addresses of Food and Drug Administration employees, which shall not be disclosed under § 20.110.

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Food and Drug Administration operates two public reading rooms. The Freedom of Information Staff's Public Reading Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, the phone number is 301–827–6500. The Division of Dockets Management's Public Reading Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852; the phone number is 301–827–6860. Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

(b) The following records are available at the Freedom of Information Staff's Public Reading Room:

(1) A guide for making requests for records or information from the Food and Drug Administration;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Food and Drug Administration records which have been released to any person in response to a Freedom of Information request and which the agency has determined have become or are likely to become the subject of subsequent requests for substantially the same records;

(4) Indexes of records maintained in the Freedom of Information Staff's Public Reading Room; and

(5) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(c) The following records are available in the Division of Dockets Management's Public Reading Room:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by the agency that are still in force and not published in the FEDERAL REGISTER;

(3) Indexes of records maintained in the Division of Dockets Management's Public Reading Room; and

(4) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(d) The agency will make reading room records created by the Food and Drug Administration on or after November 1, 1996, available electronically through the Internet at the agency's World Wide Web site which can be found at *http://www.fda.gov*. At the agency's discretion, the Food and Drug Administration may also make available through the Internet such additional records and information it believes will be useful to the public.

[68 FR 25287, May 12, 2003; 68 FR 65392, Nov. 20, 2003]

PART 21—PROTECTION OF PRIVACY

Subpart A—General Provisions

Sec.
21.1 Scope.
21.3 Definitions.
21.10 Policy concerning records about individuals.

Subpart B—Food and Drug Administration Privacy Act Record Systems

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

Subpart C—Requirements for Specific Categories of Records

21.30 Records of contractors.
21.31 Records stored by the National Archives and Records Administration.
21.32 Personnel records.
21.33 Medical records.

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

21.40 Procedures for submitting requests for notification and access.
21.41 Processing of requests.
21.42 Responses to requests.
21.43 Access to requested records.
21.44 Verification of identity.
21.45 Fees.

Subpart E—Procedures for Requests for Amendment of Records

21.50 Procedures for submitting requests for amendment of records.
21.51 Responses to requests for amendment of records.
21.52 Administrative appeals of refusals to amend records.
21.53 Notation and disclosure of disputed records.
21.54 Amended or disputed records received from other agencies.

Subpart F—Exemptions

21.60 Policy.
21.61 Exempt systems.
21.65 Access to records in exempt systems.

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

21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.
21.71 Disclosure of records in Privacy Act Record Systems; accounting required.
21.72 Individual consent to disclosure of records to other persons.
21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.
21.74 Providing notice that a record is disputed.
21.75 Rights of legal guardians.

AUTHORITY: 21 U.S.C. 371; 5 U.S.C. 552, 552a.

SOURCE: 42 FR 15626, Mar. 22, 1977, unless otherwise noted.