

§ 20.80

21 CFR Ch. I (4–1–00 Edition)

investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(b) Records include all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records prior to public disclosure only pursuant to § 20.32.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in subpart D of this part is available for such disclosure to the extent that it

falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(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 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 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 subject to the special requirements of part 21, 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 21, subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in

§ 20.82

§20.44 shall be accompanied by a statement that the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 59 FR 536, Jan. 5, 1994]

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that is:

(1) Exempt from public disclosure pursuant to §20.61.

(2) Exempt from public disclosure pursuant to §20.63.

(3) Prohibited from public disclosure pursuant to 21 U.S.C. 331(j), 42 U.S.C. 263g(d), 42 U.S.C. 263i, or 18 U.S.C. 1905.

(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 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

(c) Discretionary disclosure of a record pursuant to this section shall invoke the requirement that the record shall be disclosed to any person who requests it pursuant to §20.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to

21 CFR Ch. I (4-1-00 Edition)

disclose any other record that is exempt from disclosure.

§ 20.83 Disclosure required by court order.

(a) Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in §20.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

(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 §20.63, 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.

§ 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and

Food and Drug Administration, HHS

§ 20.88

confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360(j)(c), 42 U.S.C. 263g(d) and 42 U.S.C. 263i(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.

[47 FR 10804, Mar. 12, 1982, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 38633, July 27, 1995]

§ 20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status

with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

(d)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate

§ 20.88

21 CFR Ch. I (4-1-00 Edition)

to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to State government officials as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes one or more of the following determinations:

(A) The sponsor of the product application has provided written authorization for the disclosure;

(B) Disclosure would be in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State government being able to exercise its regulatory authority more expeditiously than the Food and Drug Administration; or

(C) The disclosure is to a State government scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the Federal Food, Drug, and Cosmetic Act (the act), the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting State government scientist to sign a written commitment to protect the confidentiality of the information, and the visiting State government scientist provides a written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the individual were subject to the conflict of

interest rules applicable to the Food and Drug Administration advisory committee members under §14.80(b)(1) of this chapter. Subject to all the foregoing conditions, a visiting State government scientist may have access to trade secret information, entitled to protection under section 301(j) of the act, in those cases where such disclosures would be a necessary part of the joint review or training.

(2) Except as provided under paragraph (d)(1)(ii)(C) of this section, this provision does not authorize the disclosure to State government officials of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the act, unless pursuant to an express written authorization provided by the submitter of the information.

(3) Any disclosure under this section of information submitted to the Food and Drug Administration or incorporated into agency-prepared records does not invoke the rule established in §20.21 that such records shall be made available to all members of the public.

(e)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a State government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements, provided that:

(i) The State government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written

Food and Drug Administration, HHS

§ 20.89

confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established at §20.21 that such records shall be made available to all members of the public.

(3) For purposes of this paragraph, the term *official of a State government agency* includes, but is not limited to, an agent contracted by the State government, and an employee of an organization of State officials having responsibility to facilitate harmonization of State standards and requirements in FDA's areas of responsibility. For such officials, the statement and commitment required by paragraph (e)(1)(i) of this section shall be provided by both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 63381, Dec. 8, 1995; 65 FR 11887, Mar. 7, 2000]

EFFECTIVE DATE NOTE: At 65 FR 11887, Mar. 7, 2000, §20.88 was amended by revising paragraph (e)(1), effective May 22, 2000. For the convenience of the user, the superseded text is set forth as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(e)(1) The Deputy Commissioner for Policy, or any other officer or employee of the Food and Drug Administration whom the Deputy Commissioner for Policy may designate to act on his or her behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a State government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State uniformity, cooperative regulatory activities, or implementa-

tion of Federal-State agreements, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect such nonpublic documents from public disclosure and a written commitment not to disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Deputy Commissioner for Policy or the Deputy Commissioner for Policy's designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements.

* * * * *

§ 20.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the foreign government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(b) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country as part of cooperative law enforcement efforts does not invoke the rule established in §20.21 that such records shall be made

§ 20.89

21 CFR Ch. I (4–1–00 Edition)

available for disclosure to all members of the public.

(c)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to foreign government officials who perform counterpart functions to the Food and Drug Administration as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The foreign government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee makes one or more of the following determinations:

(A) The sponsor of the product application has provided written authorization for the disclosure;

(B) Disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation; or

(C) The disclosure is to a foreign scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the act, the review is in the interest of public health, the Food and Drug Administration retains physical control over the information, the Food and Drug Administration requires the visiting foreign scientist to sign a written commitment to protect the confidentiality of the information, and the scientist provides a written assurance that he or she has no financial interest in the regulated industry of the type that would preclude participation in the review of the matter if the

individual were subject to the conflict of interest rules applicable to the Food and Drug Administration advisory committee members under § 14.80(b)(1) of this chapter. Subject to all of the foregoing conditions, visiting foreign scientists may have access to trade secret information, entitled to protection under section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act), in those cases where such disclosures would be a necessary part of the joint review or training.

(2) Except as provided under paragraph (c)(1)(ii)(C) of this section, this provision does not authorize the disclosure to foreign government officials of other countries of trade secret information concerning manufacturing methods and processes prohibited from disclosure by section 301(j) of the act, unless pursuant to an express written authorization provided by the submitter of the information.

(3) Any disclosure under this section of information submitted to the Food and Drug Administration or incorporated into agency-prepared records does not invoke the rule established in § 20.21 that such records shall be made available to all members of the public.

(d)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

Food and Drug Administration, HHS

§ 20.90

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

(2) Any exchange under this section of nonpublic documents does not invoke the rule established in §20.21 that such records shall be made available to all members of the public.

(3) For purposes of this paragraph, the term *official of a foreign government agency* includes, but is not limited to, an agent contracted by the foreign government, and an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility. For such officials, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.

(e) For purposes of this section, the term "official of a foreign government agency" includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

[42 FR 15616, Mar. 22, 1977, as amended at 58 FR 61603, Nov. 19, 1993; 60 FR 63382, Dec. 8, 1995; 65 FR 11888, Mar. 7, 2000]

EFFECTIVE DATE NOTE: At 65 FR 11888, Mar. 7, 2000, §20.89 was amended by revising paragraph (d)(1); by removing paragraph (d)(3); and by adding paragraph (e), effective May 22, 2000. For the convenience of the user, the superseded text is set forth as follows:

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) The Deputy Commissioner for Policy, or any other officer or employee of the Food and Drug Administration whom the Deputy Commissioner for Policy may designate to act on his or her behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

(i) The foreign government agency has provided both a written statement establishing its authority to protect such nonpublic documents from public disclosure and a written commitment not to disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

(ii) The Deputy Commissioner for Policy or the Deputy Commissioner for Policy's designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

* * * * *

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

§ 20.91

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

- (1) Restrictions on access to the data and information by the contractor, its employees, or other persons;
- (2) Physical storage requirements;
- (3) Requirements for the handling and accountability of the data and information by the contractor and its employees;
- (4) Limitations on reproduction, transmission, and disclosure of the data and information;
- (5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;
- (6) Procedures to be followed when the contractor employs time-shared computer operations;
- (7) Methods of destroying source documents or related waste material; and
- (8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

21 CFR Ch. I (4-1-00 Edition)

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in subpart D of this part and the limitations on exemptions established in subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in subpart D of this part except as provided by the limitations on exemptions specified in subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

- (1) Section 305 hearing records, in § 7.87(c) of this chapter.
- (2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.
- (3) Environmental assessments; finding of no significant impact, in § 25.51 of this chapter, or draft and final environmental impact statements, in § 25.52 of this chapter.
- (4) Color additive petitions, in § 71.15 of this chapter.
- (5) Food standard temporary permits, in § 130.17(k) of this chapter.
- (6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 108.35(l) of this chapter.