

§ 20.82

21 CFR Ch. I (4–1–03 Edition)

§ 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 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 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

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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 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