

## Food and Drug Administration, HHS

## § 20.84

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 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; 68 FR 25287, May 12, 2003]

### § 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 under statute.

(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.

[42 FR 15616, Mar. 22, 1977, as amended at 70 FR 41958, July 21, 2005]

### § 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, in the form of a regulation published or cross-referenced in this part, 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.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25287, May 12, 2003]

### § 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.