

(e) A determination of confidentiality pursuant to this section is subject to the limitations established in subpart E of this part except that the data or information involved shall not be subject to discretionary release pursuant to § 20.82. Such a determination of confidentiality by the Food and Drug Administration means that the Food and Drug Administration will not make the data or information involved available for public disclosure unless ordered to do so by a court.

(f) A determination based upon a pre-submission review pursuant to this section shall be made in writing and shall be signed only by the Associate Commissioner for Public Affairs.

(g) Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(h) No request under this section shall be accepted if the status of the records involved is already determined by § 20.111 or by any other regulation published or cross-referenced in this part.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 8995, Mar. 6, 1985]

§ 20.45 Situations in which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, the Food and Drug Administration will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

§ 20.46 Judicial review of proposed disclosure.

Where the Food and Drug Administration consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pursuant to § 20.45, and rejects the person's request that part or all of the records not be made available for public disclosure, the decision constitutes final agency action that is subject to judi-

cial review pursuant to 5 U.S.C. chapter 7. The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

§ 20.47 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Associate Commissioner for Public Affairs.

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Assistant Secretary for Health, Department of Health and Human Services, pursuant to the provisions of 45 CFR 5.34.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990]

§ 20.48 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search for and compile will be processed taking into account the staff-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information shall be