

§ 20.44

this effect outweighs the advancement of that public interest. In applying this second test, the Food and Drug Administration will consider the following factors:

(1) Whether disclosure would further a commercial interest of the requester, or of someone on whose behalf the requester is acting. Commercial interests include interests relating to business, trade, and profit. Both profit and non-profit-making corporations have commercial interests, as well as individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, whether that effect outweighs the advancement of the public interest as defined in paragraph (b) of this section.

(d) *Deciding between waiver and reduction.* If the disclosure of the information requested passes both tests described in paragraphs (b) and (c) of this section, the Food and Drug Administration will normally waive fees. However, in some cases the Food and Drug Administration may decide only to reduce the fees. For example, the Food and Drug Administration may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction.* A requester must request a waiver or reduction of fees at the same time as the request for records. The requester should explain why a waiver or reduction is proper under the factors set forth in paragraphs (a) through (d) of this section. Only the Associate Commissioner for Public Affairs may make the decision whether to waive or reduce the fees. If the Food and Drug Administration does not completely grant the request for a waiver or reduction, the denial letter will designate a review official. The requester may appeal the denial to that official. The appeal letter should address reasons for the Associate Commissioner's decision that are set forth in the denial letter.

[59 FR 534, Jan. 5, 1994]

21 CFR Ch. I (4-1-03 Edition)

§ 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily to the Food and Drug Administration may forward to the Director of the Center involved, or to the Associate Commissioner for Regulatory Affairs, a request for presubmission review of the records involved to determine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fall within an exemption from public disclosure set out in subpart D of this part and shall enclose the records involved.

(b) Pending a determination upon such request, the records involved shall be held confidentially and separately by the Food and Drug Administration and shall not be received as part of Food and Drug Administration files.

(c) Pursuant to such a request, the Food and Drug Administration shall make a determination whether part or all of the records involved will be made available for public disclosure upon request if they are submitted. A determination of confidentiality will be made only if it is concluded that the data or information involved fall within an exemption from public disclosure set out in subpart D of this part and are relevant to and important for agency activity.

(d) After a determination is made pursuant to this section, the Food and Drug Administration shall receive as part of its files the records for which a request for confidentiality has been granted and shall so mark or designate those records. The person requesting the presubmission review shall have the option of submitting or withdrawing the records for which a request for confidentiality has been denied. No copy or summary of records withdrawn pursuant to this section, or any correspondence or memoranda or records relating thereto, shall be retained in Food and Drug Administration files.

(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