

§ 20.46

21 CFR Ch. I (4–1–04 Edition)

(d) *Procedures for assessing and collecting fees*—(1) *Agreement to pay.* The Food and Drug Administration generally assumes that a requester is willing to pay the fees charged for services associated with the request. The requester may specify a limit on the amount to be spent. If it appears that the fees will exceed the limit, the Food and Drug Administration will consult the requester to determine whether to proceed with the search.

(2) *Advance payment.* If a requester has failed to pay previous bills in a timely fashion, or if the Food and Drug Administration's initial review of the request indicates that the charges will exceed \$250, the requester will be required to pay past due fees and/or the estimated fees, or a deposit, before the search for the requested records begins. In such cases, the requester will be notified promptly upon receipt of the request, and the administrative time limits prescribed in § 20.41 will begin only after there is an agreement with the requester over payment of fees, or a decision that fee waiver or reduction is appropriate.

(3) *Billing and payment.* Ordinarily, the requester will be required to pay all fees before the Food and Drug Administration will furnish the records. At its discretion, the Food and Drug Administration may send the requester a bill along with or following the records. For example, the Food and Drug Administration may do this if the requester has a history of prompt payment. The Food and Drug Administration may also, at its discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, the Food and Drug Administration might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to the request.

[59 FR 533, Jan. 5, 1994. Redesignated and amended at 68 FR 25286, May 12, 2003]

§ 20.46 Waiver or reduction of fees.

(a) *Standard.* The Assistant Commissioner for Public Affairs (or delegatee) will waive or reduce the fees that would otherwise be charged if disclo-

sure of the information meets both of the following tests:

(1) Is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and

(2) It is not primarily in the commercial interest of the requester. These two tests are explained in paragraphs (b) and (c) of this section.

(b) *Public interest.* Disclosure of information satisfies the first test only if it furthers the specific public interest of being likely to contribute significantly to public understanding of Government operations or activities, regardless of any other public interest it may further. In analyzing this question, the Food and Drug Administration will consider the following factors:

(1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government;

(2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;

(3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and

(4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

(c) *Not primarily in the requester's commercial interest.* If disclosure passes the test of furthering the specific public interest described in paragraph (b) of this

section, the Food and Drug Administration will determine whether disclosure also furthers the requester's commercial interest and, if so, whether 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. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.47 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.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.48 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 § 20.47, 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 judicial 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.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.49 Denial of a request for records.

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

(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.