

§ 20.45

authorized representative of the individual, and must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the individual.

(c) A request for expedited processing made under paragraph (a)(2) of this section must demonstrate that:

(1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;

(2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and

(3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

(d) All requests for expedited processing shall be filed in writing as provided by § 20.40. Each such request shall include information that demonstrates a reasonable basis for concluding that a compelling need exists within the meaning of paragraph (a) of this section and a certification that the information provided in the request is true and correct to the best of the requester's knowledge and belief. Any statements made in support of a request for expedited processing are subject to the False Reports to the Government Act (18 U.S.C. 1001).

(e) The Assistant Commissioner for Public Affairs (or delegatee) will determine whether to grant a request for expedited processing within 10 days of receipt by the Freedom of Information Staff of all information required to make a decision.

(f) If the agency grants a request for expedited processing, the agency shall process the request as soon as practicable.

(g) If the agency denies a request for expedited processing, the agency shall process the request with other non-expedited requests.

(h) If the agency denies a request for expedited processing, the requester

21 CFR Ch. I (4-1-04 Edition)

may appeal the agency's decision by writing to the official identified in the denial letter.

[68 FR 25286, May 12, 2003]

§ 20.45 Fees to be charged.

(a) *Categories of requests.* Paragraphs (a) (1) through (3) of this section state, for each category of request, the type of fees that the Food and Drug Administration will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in paragraphs (b) and (c) of this section and in § 20.46 or for other reasons.

(1) *Commercial use request.* If the request is for a commercial use, the Food and Drug Administration will charge for the costs of search, review, and duplication.

(2) *Educational and scientific institutions and news media.* If the request is from an educational institution or a noncommercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and the request is not for a commercial use, the Food and Drug Administration will charge only for the duplication of documents. Also, the Food and Drug Administration will not charge the copying costs for the first 100 pages of duplication.

(3) *Other requests.* If the request is not the kind described in paragraph (a)(1) or (a)(2) of this section, then the Food and Drug Administration will charge only for the search and the duplication. Also, the Food and Drug Administration will not charge for the first 2 hours of search time or for the copying costs of the first 100 pages of duplication.

(b) *General provisions.* (1) The Food and Drug Administration may charge search fees even if the records found are exempt from disclosure or if no records are found.

(2) If, under paragraph (a)(3) of this section, there is no charge for the first 2 hours of search time, and those 2 hours are spent on a computer search, then the 2 free hours are the first 2 hours of the operator's own operation. If the operator spends less than 2 hours on the search, the total search fees will be reduced by the average hourly rate

for the operator's time, multiplied by 2.

(3) If, under paragraph (a)(2) or (a)(3) of this section, there is no charge for the first 100 pages of duplication, then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer print-out. If this method to calculate the fee reduction cannot be used, then the total duplication fee will be reduced by the normal charge for photocopying a standard size page, multiplied by 100.

(4) No charge will be made if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee.

(5) If it is determined that a requester (acting either alone or together with others) is breaking down a single request into a series of requests in order to avoid (or reduce) the fees charged, all these requests may be aggregated for purposes of calculating the fees charged.

(6) Interest will be charged on unpaid bills beginning on the 31st day following the day the bill was sent. Provisions in 45 CFR part 30, the Department of Health and Human Services regulations governing claims collection, will be used in assessing interest, administrative costs, and penalties, and in taking actions to encourage payment.

(c) *Fee schedule.* The Food and Drug Administration charges the following fees in accordance with the regulations of the Department of Health and Human Services at 45 CFR part 5.

(1) *Manual searching for or reviewing of records.* When the search or review is performed by employees at grade GS-1 through GS-8, an hourly rate based on the salary of a GS-5, step 7, employee; when done by a GS-9 through GS-14, an hourly rate based on the salary of a GS-12, step 4, employee; and when done by a GS-15 or above, an hourly rate based on the salary of a GS-15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate for the specified grade and step, adding 16 percent of that rate to cover benefits, and rounding to the nearest whole dollar. When a search involves employees at more than one of these levels, the Food and Drug Admin-

istration will charge the rate appropriate for each.

(2) *Computer searching and printing.* The actual cost of operating the computer plus charges for the time spent by the operator, at the rates given in paragraph (c)(1) of this section.

(3) *Photocopying standard size pages.* \$0.10 per page. Freedom of Information Officers may charge lower fees for particular documents where:

(i) The document has already been printed in large numbers;

(ii) The program office determines that using existing stock to answer this request, and any other anticipated Freedom of Information requests, will not interfere with program requirements; and

(iii) The Freedom of Information Officer determines that the lower fee is adequate to recover the prorated share of the original printing costs.

(4) *Photocopying odd-size documents (such as punchcards or blueprints), or reproducing other records (such as tapes).* The actual costs of operating the machine, plus the actual cost of the materials used, plus charges for the time spent by the operator, at the rates given in paragraph (c)(1) of this section.

(5) *Certifying that records are true copies.* This service is not required by the Freedom of Information Act. If the Food and Drug Administration agrees to provide certification, there is a \$10 charge per certification.

(6) *Sending records by express mail or other special methods.* This service is not required by the Freedom of Information Act. If the Food and Drug Administration agrees to provide this service, the requester will be required to directly pay, or be directly charged by, the courier. The agency will not agree to any special delivery method that does not permit the requester to directly pay or be directly charged for the service.

(7) *Performing any other special service in connection with a request to which the Food and Drug Administration has agreed.* Actual costs of operating any machinery, plus actual cost of any materials used, plus charges for the time of the Food and Drug Administration's employees, at the rates given in paragraph (c)(1) of this section.

§ 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