

hourly rate for the specified grade and step, adding 16 percent of that rate to cover benefits, and rounding to the nearest whole dollar. As of January 1, 1993, these rates were \$12, \$24, and \$43 respectively. When a search involves employees at more than one of these levels, the Food and Drug Administration 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, certified 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, actual costs will be charged.

(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.

(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]

§ 20.43 Waiver or reduction of fees.

(a) *Standard.* The Associate Commissioner for Public Affairs will waive or

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reduce the fees that would otherwise be charged if disclosure 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 in-

terest 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

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the Associate Commissioner's decision that are set forth in the denial letter.

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§ 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 presubmission 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