

Food and Drug Administration, HHS

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writing by mailing the request or delivering it to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Freedom of Information Staff shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to § 20.41(b), and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in § 21.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for

records is logged in by the Freedom of Information Staff pursuant to § 20.40(c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Freedom of Information Staff and is logged in there in accordance with § 20.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, a letter shall be sent to the persons making the request determining whether, or to the extent which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 20.45, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3) In the following unusual circumstances, the time for sending this letter may be extended for up to an additional 10 working days by written notice to the person making the request setting forth the reasons for such extension and the time within which a determination is expected to be dispatched:

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the Freedom of Information Staff.

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request.

(iii) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or

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more components of the Food and Drug Administration having substantial subject-matter interest therein.

(4) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, Department of Health and Human Services, in accordance with the provisions of 45 CFR 5.34.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990; 59 FR 533, Jan. 5, 1994]

§ 20.42 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 § 20.43 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:

(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