

(B) There is a need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(C) There is 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 more components of the Food and Drug Administration having substantial subject-matter interest in the determination.

(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.

(c) The Food and Drug Administration shall provide a determination of whether to provide expedited processing within 10 calendar days of receipt by the Freedom of Information Staff of the request and the required documentation of compelling need in accordance with § 20.44(b).

[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; 68 FR 25285, May 12, 2003]

#### § 20.42 Aggregation of certain requests.

The Food and Drug Administration may aggregate certain requests by the same requester, or by a group of requesters acting in concert, if the requests involve clearly related matters and the agency reasonably believes that such requests actually constitute a single request which would otherwise satisfy the unusual circumstances specified in § 20.41(b)(3)(ii)(B). FDA may extend the time for processing aggregated requests in accordance with the unusual circumstances provisions of § 20.41.

[68 FR 25286, May 12, 2003]

#### § 20.43 Multitrack processing.

(a) Each Food and Drug Administration component is responsible for determining whether to use a multitrack system to process requests for records maintained by that component. A multitrack system provides two or more

tracks for processing requests, based on the amount of work and/or time required for a request to be processed. The availability of multitrack processing does not affect expedited processing in accordance with § 20.44.

(b) If multitrack processing is not adopted by a particular agency component, that component will process all requests in a single track, ordinarily on a first-in, first-out basis.

(c) If a multitrack processing system is established by a particular agency component, that component may determine how many tracks to establish and the specific criteria for assigning requests to each track. Multiple tracks may be established for requests based on the amount of work and/or time required for a request to be processed.

(d) Requests assigned to a given track will ordinarily be processed on a first-in, first-out basis within that track.

(e) If a request does not qualify for the fastest processing track, the requester may be provided an opportunity to limit the scope of the request in order to qualify for faster processing.

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#### § 20.44 Expedited processing.

(a) The Food and Drug Administration will provide expedited processing of a request for records when the requester demonstrates a compelling need, or in other cases as determined by the agency. A compelling need exists when:

(1) A failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity.

(b) A request for expedited processing made under paragraph (a)(1) of this section must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other

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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

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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