e.g., because it is necessary to consult the person affected pursuant to § 20.47, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3)(i) In unusual circumstances, the agency may extend the time for sending the letter for an additional period.

(A) The agency may provide for an extension of up to 10 working days by providing written notice to the requester setting out the reasons for the extension and the date by which a determination is expected to be sent.

(B) The agency may provide for an extension of more than 10 working days by providing written notice to the requester setting out the reasons for the extension. The notice also will give the requester an opportunity to limit the scope of the request so that it may be processed in a shorter time and/or an opportunity to agree on a timeframe longer than the 10 extra working days for processing the request.

(ii) Unusual circumstances may exist under any of the following conditions:

(A) There is a need to search for and collect the requested records from field facilities or other components that are separate from the agency component responsible for processing the request;

(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 § 20.44(b).

§ 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)(i)(B). FDA may extend the time for processing aggregated requests in accordance with the unusual circumstances provisions of § 20.41.

§ 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 will process all requests in a single track, ordinarily on a first-in, first-out basis.

(d) Requests assigned to a given track will ordinarily be processed on a first-in, first-out basis within that track.
§ 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 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 may appeal the agency’s decision by writing to the official identified in the denial letter.

§ 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,