

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.

\* \* \* \* \*

(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).

■ 15. Sections 20.45 through 20.53 are redesignated as §§ 20.47 through 20.55, §§ 20.42 and 20.43 are redesignated as §§ 20.45 and 20.46, new §§ 20.42 and 20.43 are added, and § 20.44 is revised, to read as follows:

#### **§ 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.

#### **§ 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.

#### **§ 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 nonexpedited 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.

■ 16. Newly redesignated § 20.45 is amended in paragraph (a) introductory text by removing "§ 20.43" and by adding in its place "§ 20.46", by revising the introductory text of paragraph (c), by removing the third sentence in paragraph (c)(1), and by revising paragraph (c)(6) to read as follows:

#### **§ 20.45 Fees to be charged.**

\* \* \* \* \*

(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.

\* \* \* \* \*

(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