Pipelines, Reporting and recordkeeping requirements.

By direction of the Commission.

David P. Boergers,

Secretary.

In consideration of the foregoing, the Commission proposes to amend Parts 141 and 385, Chapter I, Title 18, of the Code of Federal Regulations, as follows:

PART 141—STATEMENTS AND REPORTS (SCHEDULES)

1. The authority citation for Part 141 continues to read as follows:

Authority: 15 U.S.C. 79; 16 U.S.C. 791a–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. Section 141.51 is amended by revising paragraph (c) to read as follows:

§ 141.51 FERC Form No. 714, Annual Electric Control and Planning Area Report.

* * * * *

(c) *What to file.* FERC Form No. 714, ''Annual Electric Control and Planning Area Report,'' must be filed with the Commission as prescribed in § 385.2011 and as indicated in the general instructions set out in this report form, and must be properly completed and verified. Filing on electronic media pursuant to § 385.2011 will be required commencing with the report required to be submitted for the reporting year 1999, to be submitted on or before June 1, 2000.

3. Section 141.61 is revised to read as follows:

§ 141.61 FERC Form No. 423, Monthly Report of Cost and Quality of Fuels for Electric Plants.

(a) *Who must file.* Every electric power producer having electric generating plants with a rated steam-electric generating capacity of 50 megawatts or greater during the reporting month must file with the Federal Energy Regulatory Commission for each such plant the FERC Form No. 423, ''Monthly Report of Cost and Quality of Fuels for Electric Plants,'' pursuant to the General Instructions set out in that form.

(b) *When to file and what to file.* This report form must be filed on or before the 45th day after the end of each reporting month. This report form must be filed with the Federal Energy Regulatory Commission as prescribed in § 385.2011 and as indicated in the general instructions set out in this report form, and must be properly completed and verified. Filing on electronic media pursuant to § 385.2011 will be required commencing with the report required to be submitted for the reporting period of January 2000.

4. Section 141.300 is amended by revising paragraphs (b) and (c) to read as follows:

§ 141.300 FERC Form No. 715, Annual Transmission Planning and Evaluation Report.

* * * * *

(b) *When to file.* FERC Form No. 715 must be filed on or before April 1 for the preceding calendar year.

(c) *What to file.* FERC Form No. 715 must be filed with the Federal Energy Regulatory Commission as prescribed in § 385.2011 and as indicated in the general instructions set out in this report form, and must be properly completed and verified. Filing on electronic media pursuant to § 385.2011 of this chapter will be required commencing with the report required to be submitted for the reporting year of 1999, to be submitted on or before April 1, 2000.

PART 385—RULES OF PRACTICE AND PROCEDURE

5. The authority citation for Part 385 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

6. Section 385.2011 is amended by adding paragraphs (a)(7), (a)(8), and (a)(9) and by revising paragraph (c)(3) to read as follows:

§ 385.2011 Procedures for filing on electronic media (Rule 2011).

(a) * * *

(7) FERC Form No. 423, Monthly report of cost and quality of fuels for electric plants (No paper copies required).

(8) FERC Form No. 714, Annual electric control and planning area report (No paper copies required).

(9) FERC Form No. 715, Annual transmission planning and evaluation report (No paper copies required).

* * * * *

(c) * * *

(3) The electronic media must be accompanied by the traditional prescribed numbers of paper copies, unless otherwise provided in paragraph (a) of this section.

* * * * *

[FR Doc. 99–28821 Filed 11–3–99; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 99N–2637]

Public Information Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its public information regulations to comply with the requirements of the Electronic Freedom of Information Act Amendments of 1996 (EFOIA). EFOIA is designed to broaden public access to government documents by making them more accessible in electronic form and by streamlining the process by which agencies generally disclose information.

DATES: Written comments by February 2, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Betty B. Dorsey, Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6567.

SUPPLEMENTARY INFORMATION:

I. Background

On October 2, 1996, the President signed into law the EFOIA (Public Law 104–231). EFOIA authorizes, and in some instances requires, agencies to issue regulations implementing certain of its provisions, including provisions regarding the aggregation of Freedom of Information Act (FOIA) requests, the expedited processing of FOIA requests, and the establishment of separate queues for the processing of FOIA requests. In addition, EFOIA amends the time limits for responding to a FOIA request from 10 to 20 working days, the process by which an agency may extend the time for responding to an FOIA request, and the requirements for reporting on FOIA activities. EFOIA also includes provisions regarding the availability of records in electronic form and the establishment of ''electronic reading rooms,'' as well as provisions requiring agencies to inform requesters about the amount of information not being released to them. FDA is proposing to amend its Public Information Regulations (part 20 (21 CFR part 20)) to implement EFOIA and

to clarify and update certain provisions unrelated to EFOIA.

II. Proposed New and Revised Provisions

A. Proposed Changes to FDA's Public Information Regulations to Implement EFOIA

The proposed rule would make the following changes to FDA's Public Information Regulations to implement EFOIA:

1. Definitions

New definitions will be added for the following terms:

a. *''Record''*—section 3 of EFOIA amends 5 U.S.C. 552(f) to define ''record'' for purposes of FOIA as including any information that would be an agency record subject to the requirements of 5 U.S.C. 552 (FOIA) when maintained by an agency in any format, including an electronic format. Section 20.20 will be revised to incorporate this definition.

b. *''Search''*—section 5 of EFOIA amends 5 U.S.C. 552(a)(3) to clarify that when an FOIA request is received, an agency should not only search for hard copies, but should also make reasonable efforts to search for records in their electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems. This provision will be implemented at § 20.34.

2. Information Provided When the Agency Makes a Denial or Partial Disclosure

The amendments (5 U.S.C. 552(a)(6)(F)), require agencies to make a reasonable effort to estimate the volume of any records that are denied either in whole or in part, and to provide the estimate to the requester, unless providing such an estimate would harm an interest protected by an FOIA exemption. FDA will provide an estimate of the volume of records denied if the volume is not otherwise indicated through deletions on records disclosed in part. Such estimates will be provided in terms of number of pages or some other reasonable measure. FDA will implement this new requirement at § 20.49(c).

Additionally, EFOIA amends 5 U.S.C. 552(b) by adding the requirement that when an agency withholds only a portion of a record, the agency shall indicate the amount of information deleted on the released portion of the record to the extent possible, except where doing so would harm an interest protected by an FOIA exemption. If technically feasible, FDA will indicate the amount of information deleted at the place in the record where the deletion is made.

The purpose of this deletion specification requirement is to make it readily apparent to a requester that a deletion has been made. When possible, the extent of the deletion will ordinarily be indicated through the use of some self-evident means. For example, a deletion may be shown by physically obscuring or removing the nondisclosable information by covering the text or figure with opaque marker or dark colored editing tape, cutting out a portion of a microfiche, or by describing in writing the extent of the deletion (e.g., ''pages 3 through 7 are not disclosable''). In those cases in which a record is provided on disk, tape, or in some other electronic form, deletions may also be indicated by using special characters or other indicators. This requirement will be implemented at § 20.22(b).

3. Electronic Reading Room Information and Indexes

Section 4 of EFOIA amends 5 U.S.C. 552(a)(2) which requires agencies to make available for public inspection and copying certain information, such as final agency opinions and orders, certain statements of policy and interpretations, and administrative staff manuals and instructions that affect a member of the public. EFOIA (5 U.S.C. 552(a)(2)(D)) adds a new category of records that agencies must make available in their public reading rooms. This new category consists of copies of records which have been released to any person under FOIA and which, because of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records. (Examples of such records at FDA might include warning letters and product approval packages.) EFOIA further requires agencies to make available for public inspection and copying a general index of frequently requested records. In addition, EFOIA requires agencies to make available by ''computer telecommunications'' (or by other electronic means, if computer telecommunications means have not been established) all reading room records that were created on or after November 1, 1996, as well as the general index of frequently requested records. FDA will implement these EFOIA requirements at §§ 20.26(a)(4) and 20.120. In addition, at its discretion, the agency may also make available other records and information that EFOIA does not require to be made available on the agency's website but which may be useful to the public. FDA's electronic FOI reading room can be accessed on the Internet through the World Wide Web at http://www.fda.gov.

4. Form or Format of FDA's Response

Section 5 of EFOIA amends 5 U.S.C. 552(a)(3) by adding the requirement for agencies making records available under FOIA to do so ''in the form or format requested by the person if the record is readily reproducible by the agency'' in the requested form or format. ''Form'' refers to the medium in which the record will be provided, such as paper, microfiche, floppy diskette, CD–ROM, or tape. ''Format'' refers to the particular manner of storing or presenting a record within a given medium, such as a particular computer program used to generate the record. Examples would include word processing, spreadsheet, data base or graphics programs and the specific software used.

When converting a record from one form or format to another, the agency will not be required to make special efforts to ensure that the physical appearance of the record is preserved. This means that in some cases, such as when the document contains tables, the appearance of the converted record may vary from the original. If the agency is unable to accommodate a particular request, the requester may be given an opportunity to choose from available alternative forms or formats. If the requester does not express a preference for an alternative form or format, the agency may choose the form or format in which the records will be provided.

FDA's FOIA operations are decentralized and each component office is responsible for responding to FOIA requests for the materials maintained by that office. These component offices shall make reasonable efforts to maintain their records in forms or formats that are readily reproducible for FOIA purposes. Because of the wide range of possible forms and formats, a specific agency component responding to an FOIA request may not have the means to provide records in all requested forms and formats. Agency components are not required to purchase special equipment or software to accommodate a request for a particular form or format, and are not required to send records to another component to accommodate an FOIA request. The agency is striving toward a common records filing structure that will enhance the agency's ability to respond to requests for records in a particular form or format. FDA will implement EFOIA's form and format requirement at § 20.33.

5. Search for Records

Section 5 of EFOIA amends 5 U.S.C. 552(a)(3) to clarify that when an FOIA request is received, an agency should not only search for hard copies, but should also make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems. Under § 20.34, the agency makes clear that searches for records include and extend to records maintained in an electronic form or format. FDA has included such records in its searches under FOIA for many years, so this provision simply clarifies and formalizes existing practice. The agency will not search for electronic records when to do so would significantly interfere with the operation of the agency's automated information systems. Decisions about when there is significant interference will be made on a case-by-case basis.

6. Time Limits for Responding to Requests

EFOIA amends 5 U.S.C. 552(a)(6)(A)(i) by increasing the time to respond to an FOIA request from 10 to 20 working days. Section 20.41(b) will be revised to reflect this change.

7. Unusual Circumstances

FOIA (5 U.S.C. 552(a)(6)(B)), permits agencies to extend the initial time limit for responding in ''unusual circumstances.'' FOIA specifies various reasons for such an extension. These reasons include the need to search for and collect records from field facilities or other components that are separate from the office processing the request; the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; and the need for consultation among two or more components of FDA, or with another Federal agency having a substantial interest in the determination of the request. In unusual circumstances, the agency may extend the time for informing a requester, by written notice, of the agency's determination of the extent to which the agency will comply with or deny an FOIA request for an additional period beyond the normal 20 days. The agency may extend the time for a response by up to an additional 10 days by providing a written notice to the requester. If the agency is unable to comply within the additional 10 days, the agency may further extend the time for a response by notifying the requester and providing the requester an opportunity to limit the scope of the request so that it can be processed in a shorter time, and/or an opportunity to agree to an alternative timeframe for processing the request. In the event there is a legal dispute concerning a request, section 6(c)(iii) of EFOIA requires the court to take into account a requester's failure to modify the request or arrange for an alternative timeframe when determining whether ''exceptional circumstances'' exist. When exceptional circumstances exist, the court may allow the agency additional time to complete its processing of the request. FDA will implement this provision at § 20.41(b)(3).

8. Aggregation of Certain Requests

Section 7 of EFOIA provides at 5 U.S.C. 552(a)(6)(B)(iv) that agencies may issue regulations allowing for the aggregation of certain FOIA requests by the same requester or by a group of requesters acting together, if the agency reasonably believes that such requests actually constitute a single request, which would otherwise satisfy the unusual circumstances that could justify an extension of the response time. FDA has decided to issue such a regulation and will do so at § 20.42.

9. Multitrack Processing

Section 7 of EFOIA (5 U.S.C. 552(a)(6)(D)(i)) authorizes agencies that experience difficulties in meeting FOIA's time limits to issue regulations providing for multitrack processing of FOIA requests rather than processing them on a first-in, first-out basis. 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 purpose of multitrack processing is to promote faster and more efficient processing of FOIA requests.

As amended, FDA regulations would permit, but not require, each FDA component to establish a multitrack processing system for responding to FOIA requests. Because FDA has a decentralized system for processing FOIA requests, the agency will allow each of its component offices to make its own decision on whether to use a multitrack processing system or single track processing system. The nature and volume of FOIA requests received and the types of records maintained can differ greatly from one FDA component to another. If a component does choose multitrack processing, that component may determine how many tracks to establish and the specific criteria for assigning requests to each track. Requests assigned to a given track generally will be processed on a first-in, first-out basis within that track. Although requests assigned to a faster track will ordinarily have a faster response time than requests assigned to other tracks, the agency will exercise due diligence in processing all requests, regardless of track. The requester may be provided an opportunity to limit the scope of the request in order to qualify for a faster processing track. If a component chooses not to establish multitrack processing, it ordinarily will use a first-in, first-out single track processing system. This provision will be implemented at § 20.43.

10. Expedited Processing

Section 8 of EFOIA (5 U.S.C. 552(a)(6)(E)) requires agencies to issue regulations to provide for expedited processing of FOIA requests in cases where the person requesting the records demonstrates a ''compelling need'' and in other cases as determined by the agency. The amendments define ''compelling need'' in two ways. One way is where ''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.'' The other way is ''with respect to a request made by a person primarily engaged in disseminating information, [there is an] urgency to inform the public concerning actual or alleged Federal Government activity.'' If a requester demonstrates a compelling need, FDA will process the request out of turn and give it expedited treatment. Granting a request for expedited processing does not constitute a promise to meet any particular deadline for responding. Rather, requests that qualify for expedited processing will be processed ''as soon as practicable.''

Where records are required to avoid an imminent threat to the life or physical safety of an individual, the request for expedited processing must be made by the individual whose life or safety is threatened, or by an authorized representative of that individual. Where records are required due to an urgency to inform the public concerning actual or alleged Federal Government activity, the requester must be primarily engaged in disseminating information to the general public and not merely to a narrow interest group. General circulation newspapers and magazines, and radio and television stations are examples of media that are primarily engaged in disseminating information to the general public. In addition, the requested records should pertain to a matter of current exigency to the public and must have a value that will be lost if not obtained and disseminated

quickly. A routine publication or broadcast deadline alone shall not constitute urgency.

Requests for expedited processing must be accompanied by appropriate documentation, including the requester's certification that the information provided in the request is true and correct to best of the requester's knowledge and belief. A requester who knowingly provides false information in support of a request for expedited processing will be subject to criminal penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

Within 10 days of receipt by FDA's Freedom of Information Staff (FOI Staff) of a request for expedited processing and all documentation needed to make a decision on the request, the agency will determine whether to provide expedited processing. The agency will exercise its discretion with fairness and diligence in making a determination about whether to provide expedited processing, giving appropriate consideration to limited resources available to FDA for fulfilling FOIA requests. If the agency denies a request for expedited processing, it will process the request for records with other nonexpedited requests. A requester may appeal FDA's decision to deny expedited processing by writing to the official identified in the denial letter. This new requirement will be implemented at §§ 20.41(c) and 20.44.

B. Proposed Changes to FDA's Public Information Regulations Unrelated to EFOIA

The proposed rule would make the following changes to FDA's public information regulations unrelated to EFOIA:

1. Filing a Request for Records

Section 20.40(a) is being revised to clarify the agency's existing practice of accepting requests submitted to the FOI Staff via facsimile as well as via mail.

2. Revocation of Presubmission Review

The agency proposes to revise § 20.44 concerning presubmission review. This provision allows any person who is considering submission of data or information voluntarily to FDA to request a presubmission review of records involved to determine whether FDA will or will not make part or all of the records available for public disclosure upon request if they are submitted. The FOIA does not require this provision, and the agency has found that presubmission review has not met the underlying policy objective of encouraging the submission to the agency of information bearing on important public health and safety concerns. The provision has fallen into disuse and only rarely has been invoked in the past several years. In addition, the validity of this provision has been questioned by a Federal District Court in the case *Teich* v. *Food and Drug Admin.*, 751 F. Supp. 243 (D.D.C. 1990).

3. Fees to be Charged

Section 20.45 (formerly § 20.42) is being revised to reflect the fact that FDA's fee schedule is in accordance with the fee schedule of the Department of Health and Human Services (DHHS). Section 20.45(c)(6) of the proposed rule would require a requester who wishes to use a courier service for delivery of the agency's response to a request to directly pay, or be directly charged by, the courier service.

4. Records Available in FDA's Public Reading Rooms

Section 20.120 provides the locations and hours of operation of the agency's public reading rooms and outlines the types of records that are available there. This provision essentially summarizes existing agency practice for the convenience of the public.

5. Denial of a Request for Records and Waiver or Reduction of Fees

Sections 20.46 and 20.49 (formerly §§ 20.43 and 20.47) are being revised to indicate that the Associate Commissioner for Public Affairs may delegate his or her authority to deny a request for FDA records or to waive or reduce FOIA fees. FDA is proposing this change to increase the efficiency of its FOIA operations and to make its regulations consistent with DHHS' FOIA regulations at 45 CFR part 5. Section 20.49(c) is also being revised in accordance with current DHHS procedures to indicate that appeals of FDA denials are to be sent to the Deputy Assistant Secretary for Public Affairs (Media), DHHS.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required (21 CFR 25.23(a)).

IV. Economic Impact and Regulatory Flexibility Act

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In this proposal, the agency is amending its FOIA regulations to reflect the statutory changes made by the EFOIA. The amendments allow greater flexibility to the requesters of information by providing electronic access to information and provide the agency with greater flexibility in providing the requested information through the use of electronic dissemination. The agency is required to make certain records available over the Internet to enable greater public access to this information. The agency is also permitted to adopt multitrack processing systems as a means of decreasing the overall processing time for requests. FDA is updating its record searching and retrieval fees in accordance with the most recent Federal pay increase. Despite the insignificant cost increase for those requesting information, the public will receive the benefits of greater flexibility in making requests, increased access to public information, and in certain cases, a faster agency response.

This rule is not a significant regulatory action as defined by the Executive Order, and is not subject to review under the Executive Order. This rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Furthermore, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore,

under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

V. Paperwork Reduction Act

The agency has determined that this rule does not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

VI. Request for Comments

Interested persons may, on or before February 2, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Freedom of Information Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.20 is amended by adding paragraph (e) to read as follows:

§ 20.20 Policy on disclosure of Food and Drug Administration records.

* * * * *

(e) ''Record'' and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained by the agency in any format, including an electronic format.

3. Section 20.22 is amended by redesignating the existing paragraph as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 20.22 Partial disclosure of records.

(a) * * *

(b)(1) Whenever information is deleted from a record that contains both disclosable and nondisclosable information, the amount of information deleted shall be indicated on the portion of the record that is made available, unless including that indication would harm an interest protected by an exemption under the Freedom of Information Act.

(2) When technically feasible, the amount of information deleted shall be indicated at the place in the record where the deletion is made.

4. Section 20.26 is amended by adding new paragraph (a)(4) and by revising paragraph (b) to read as follows:

§ 20.26 Indexes of certain records.

(a) * * *

(4) Records which have been released to any person in response to a Freedom of Information request and which the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available through the Internet at http://www.fda.gov. A printed copy of each index is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by visiting the Freedom of Information public reading room located in rm. 12A–30 at the same address.

5. Subpart B is amended by adding §§ 20.33 and 20.34 to read as follows:

§ 20.33 Form or format of response.

(a) The Food and Drug Administration shall make reasonable efforts to provide a record in any requested form or format if the record is readily reproducible by the agency in that form or format.

(b) If the agency determines that a record is not readily reproducible in the requested form or format, the agency may notify the requester of alternative forms and formats that are available. If the requester does not express a preference for an alternative in response to such notification, the agency may provide its response in the form and format of the agency's choice.

§ 20.34 Search for records.

(a) In responding to a request for records, the Food and Drug Administration shall make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

(b) The term ''search'' means to review, manually or by automated means, agency records for the purpose of locating those records that are responsive to the request.

6. Section 20.40 is amended by revising paragraph (a) to read as follows:

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by faxing it to 301–443–1726. All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

* * * * *

7. Section 20.41 is amended by revising the introductory text of paragraph (b) and paragraph (b)(3), and by adding new paragraph (c) to read as follows:

§ 20.41 Time limitations.

* * * * *

(b) Within 20 working days (excluding Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, the agency shall send a letter to the requester providing the agency's determination as to whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons for the denial.

* * * * *

(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 which are demanded in a single request; or

(C) There is a 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).

8. 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 newly redesignated § 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 Associate 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.

9. Newly redesignated § 20.45 is amended 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 not permit the requester to directly pay or be directly charged for the service.

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10. Newly redesignated § 20.46 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 20.46 Waiver or reduction of fees.

(a) *Standard.* The Associate Commissioner for Public Affairs (or delegatee) will waive or reduce the fees that would otherwise be charged if disclosure of the information meets both of the following tests:

* * * * *

11. Newly redesignated § 20.49 is amended by revising paragraphs (a) and (c) to read as follows:

§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Associate Commissioner for Public Affairs (or delegatee).

* * * * *

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

* * * * *

12. Section 20.107 is amended by revising paragraph (a) to read as follows:

§ 20.107 Food and Drug Administration manuals.

(a) Food and Drug Administration administrative staff manuals and instructions that affect a member of the public are available for public disclosure. An index of all such manuals is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by visiting the Freedom of Information public reading room, located in rm. 12A–30 at the same address. The index and all manuals created by the agency on or after November 1, 1996, will be made available through the Internet at http://www.fda.gov.

* * * * *

13. Section 20.120 is added to subpart F to read as follows:

§ 20.120 Records available in Food and Drug Administration Public Reading Rooms.

(a) The Food and Drug Administration operates two public reading rooms. The Freedom of Information Staff's public reading room is located at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857; the phone number is 301–827–6500. The Dockets Management Branch's public reading room is located at 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; the phone number is 301–827–6860. Both public reading rooms are open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal public holidays.

(b) The following records are available at the Freedom of Information Staff's public reading room:

(1) A guide for making requests for records or information from the Food and Drug Administration;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Food and Drug Administration records which have been released to any person in response to a Freedom of Information request and which the agency has determined have become or are likely to become the subject of subsequent requests for substantially the same records;

(4) Indexes of records maintained in the Freedom of Information Staff's public reading room; and

(5) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(c) The following records are available in the Dockets Management Branch's public reading room:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by the agency that are still in force and not published in the **Federal Register**;

(3) Indexes of records maintained in the Dockets Management Branch's public reading room; and

(4) Such other records and information as the agency determines are appropriate for inclusion in the public reading room.

(d) The agency will make reading room records created by the Food and Drug Administration on or after November 1, 1996, available electronically through the Internet at the agency's World Wide Web site which can be found at http://www.fda.gov. At the agency's discretion, the Food and Drug Administration may also make available through the Internet such additional records and information as it believes will be useful to the public.

Dated: September 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28857 Filed 11–3–99; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–2303, MM Docket No. 99–318, RM–9745]

Digital Television Broadcast Service; Panama City, FL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Waitt License Company of Florida, Inc., licensee of station WPGX (TV), NTSC Channel 28, Panama City, Florida, proposing the substitution of DTV Channel 9 for station WPGX's assigned DTV Channel 29c. DTV Channel 9 can be substituted and allotted to Panama City, Florida, as proposed, in compliance with the principle community requirements of Section 73.625(a) at coordinates 30–23–42 N. and 85–32–02 W. DTV Channel 9 can be allotted to Panama City with a power of 100 (kW) and a height above average terrain (HAAT) of 207 meters.

DATES: Comments must be filed on or before December 23, 1999, and reply comments on or before January 7, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Lawrence Bernstein, 1818 N Street, NW, Suite 700, Washington, DC 20036 (Counsel for Waitt License Company of Florida, Inc.).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–318, adopted October 29, 1999, and released November 1, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, S.W., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter