

(2) If any cracking is detected, prior to further flight, accomplish the requirements of either paragraph (b)(2)(i) or (b)(2)(ii) of this AD.

(i) Replace the cracked fuse pin with a new straight fuse pin, P/N 311N5067-1, and prior to the accumulation of 2,500 total flight cycles on the newly installed straight fuse pin, perform an eddy current inspection to detect fatigue cracking in the new straight fuse pin, in accordance with the procedures described in the alert service bulletin. Repeat this inspection thereafter at intervals not to exceed 750 flight cycles on the newly installed straight fuse pin. Or

(ii) Replace the cracked fuse pin with a new 15-5PH fuse pin, P/N 311N5217-1, and prior to the accumulation of 14,000 total flight cycles on the newly installed 15-5PH fuse pin, perform an eddy current inspection to detect fatigue cracking in the fuse pin, in accordance with the procedures described in the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 3,500 flight cycles on the newly installed 15-5PH fuse pin.

(c) For airplanes equipped with bulkhead fuse pins, P/N 311N5211-1: Within 3,000 flight cycles on the bulkhead fuse pins after April 10, 1996 (the effective date of AD 96-05-08, amendment 39-9534), replace the bulkhead fuse pin with a new 15-5PH fuse pin, P/N 311N5217-1, in accordance with Boeing Service Bulletin 757-54A0020, Revision 5, dated March 17, 1994, or Boeing Alert Service Bulletin 757-54A0020, Revision 6, dated July 18, 1997, and accomplish the requirements of paragraph (d) of this AD.

(d) For airplanes equipped with 15-5PH fuse pins: Prior to the accumulation of 14,000 total flight cycles on the 15-5PH fuse pins, perform an eddy current inspection to detect fatigue cracking in those fuse pins, in accordance with the procedures described in Boeing Alert Service Bulletin 757-54A0020, Revision 6, dated July 18, 1997.

(1) If no cracking is detected, repeat the inspection thereafter at intervals not to exceed 3,500 flight cycles on the 15-5PH fuse pin.

(2) If any cracking is detected, prior to further flight, replace the cracked 15-5PH fuse pin with a new 15-5PH fuse pin, P/N 311N5217-1, and prior to the accumulation of 14,000 total flight cycles on the newly installed 15-5PH fuse pin, perform an eddy current inspection to detect fatigue cracking in the newly installed 15-5PH fuse pin; in accordance with the procedures described in the alert service bulletin. Repeat the inspection thereafter at intervals not to exceed 3,500 flight cycles on the newly installed 15-5PH fuse pin.

(e) Fuse pins must be of the same type on the same strut. For example, a steel fuse pin having P/N 311N5067-1 may not be installed on the same strut that has a 15-5PH fuse pin having P/N 311N5217-1 installed on that strut. However, fuse pins on one strut may differ from those on another strut, provided the fuse pins are not of mixed types on the same strut.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be

used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(h) The inspections and replacements shall be done in accordance with Boeing Service Bulletin 757-54A0020, Revision 5, dated March 17, 1994, or Boeing Alert Service Bulletin 757-54A0020, Revision 6, dated July 18, 1997.

(1) The incorporation by reference of Boeing Alert Service Bulletin 757-54A0020, Revision 6, dated July 18, 1997, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Boeing Service Bulletin 757-54A0020, Revision 5, dated March 17, 1994, was approved previously by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of April 10, 1996 (61 FR 9601, March 11, 1996).

(3) Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) This amendment becomes effective on September 17, 1997.

Issued in Renton, Washington, on August 21, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1015

#### Procedures for Disclosure or Production of Information Under the Freedom of Information Act; Amendments

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Electronic Freedom of Information Act Amendments of 1996, which amend the Freedom of Information Act, are designed to make

government documents more accessible to the public in electronic form. The amendments are also intended to expedite and streamline the process by which agencies disclose information generally. In this notice, the Commission amends its Freedom of Information Act regulations to comply with the requirements of the new statute.

**DATES:** The amendments become effective on October 2, 1997.

**FOR FURTHER INFORMATION CONTACT:** Jayme Rizzolo Epstein, Office of the General Counsel, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0980; or Todd Stevenson, Freedom of Information Officer, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0800.

#### SUPPLEMENTARY INFORMATION:

##### Background Information

On October 2, 1996, the President signed into law the Electronic Freedom of Information Act Amendments of 1996 ("EFOIA"), Public Law 231, 110 Stat. 3048 (1996). EFOIA includes provisions authorizing or requiring agencies to promulgate regulations implementing certain of its requirements, including the tracking of Freedom of Information Act ("FOIA") requests, the aggregation of FOIA requests, and the expedited processing of FOIA requests. In addition, EFOIA changes the time limit for responding to a FOIA request from ten to twenty days, the requirements for reporting on FOIA activities to Congress, and the cases in which an agency may extend the time for responding to a FOIA request. EFOIA also includes provisions regarding the availability of documents in electronic form, the treatment of electronic records, and the establishment of "electronic reading rooms."

On May 6, 1997 the Consumer Product Safety Commission ("Commission") proposed amendments to its regulations implementing the Freedom of Information Act, 16 CFR Part 1015. See 62 FR 24614, May 6, 1997. The proposed amendments were intended to revise the Commission's FOIA regulations to comply with EFOIA. The Commission received three comments in response to the proposed amendments. The comments are discussed below. The Commission now issues the amendments in final form. They are identical to the proposed amendments, except for a few changed words in §§ 1015.2 and 1015.5(f) that clarify the meaning of those provisions.

## New Provisions

### A. Electronic Records

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. section 552] when maintained by an agency in any format, including an electronic format." Section 552(f) thus clarifies that the term "agency record" includes information stored on or by computers as well as traditional paper documents. The regulations amend 16 CFR 1015.1(a) by adding language to reflect this definition of "record" and to clarify that the Commission produces all releasable records responsive to a FOIA request, whether in traditional paper or electronic form.

### B. Electronic Reading Room

FOIA section 552(a)(2) requires agencies to make available for inspection and copying the following: (1) Final opinions and orders made in adjudicated cases; (2) statements of policy and interpretations not published in the **Federal Register**; and (3) administrative staff manuals and instructions to staff that affect the public. 5 U.S.C. 552(a)(2). As stated in the Commission's FOIA regulations, the Commission maintains these materials in its Public Information Center. 16 CFR 1015.2(a). EFOIA adds a fourth category to the materials that agencies must place in their reading rooms:

copies of all records \* \* \* which have been released to any person under [FOIA] and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records.

EFOIA sec. 4; 5 U.S.C. 552(a)(2)(D).

EFOIA further requires agencies to make available by "computer telecommunications" all reading room materials that are created on or after November 1, 1996. The statute envisions that each agency will ultimately have both a traditional reading room and a new "electronic reading room" on the World-Wide Web.

Section 1015.2(c) states that the Commission will post the requisite materials on its Website. Where appropriate and feasible, and as resources permit, the Commission may also place additional reading room materials on the Website.

### C. Multitrack Processing of Requests

EFOIA authorizes agencies to promulgate regulations providing for multitrack processing of requests for records based on the amount of work

and/or time involved in processing requests. EFOIA sec. 7(a); 5 U.S.C. 552(a)(6)(D)(i). This would expedite the production of records where little work or time is required. The statute states that an agency's regulations may include a provision granting a FOIA requester whose request does not qualify for the fastest multitrack processing an opportunity to limit the scope of the request in order to qualify for faster processing. 5 U.S.C. 552(6)(D)(ii).

The Commission believes that multitrack processing is the most efficient and fair way to process FOIA requests. If requests were processed on a strict first in, first out basis, easily filled requests—for example for a press release or Commission brochure—would be processed only after earlier-received, complex requests for dozens of documents located in offices throughout the Commission. The Commission currently intends to process FOIA requests on five tracks, as follows:

Track 1: Responsive documents are available in the Office of the Secretary in releasable form. Examples include press releases, Commission brochures, and cleared Commission briefing packages.

Track 2: Responsive documents are filed in one easily identifiable location, but must be located and copied, and require internal clearance. Examples include meeting logs, technical reports and contractor reports.

Track 3: Responsive documents are located in various Commission offices and require internal clearance.

Track 4: Responsive documents require both internal clearance and review by identified manufacturers pursuant to sections 6 (a) and/or (b) of the Consumer Product Safety Act, 15 U.S.C. 2055 (a) and (b). Examples include requests for information regarding Commission investigations of specific products and/or companies.

Track 5: Responsive documents are voluminous or are located in various Commission offices, and require section 6(a) and/or (b) review.

In general, when a request is received, the Freedom of Information Office will review it and categorize it for tracking purposes. Requests within each "track" will then be processed according to the date of receipt within each category. This should help further expedite responses to FOIA requests that are easier to fill. Of course, many requests are unique and will not easily fit one of the above descriptions. Others may appear to qualify for a fast track but prove complex once the search for the responsive documents is underway. As the Office of the Secretary implements and gains experience with the multitrack system, adjustments will almost certainly be required.

Pursuant to section 1015.3(e), the Office of the Secretary may contact

requesters whose requests do not appear to qualify for the fastest tracks and provide such requesters the opportunity to limit their requests so they qualify for a faster track. Such notification will be at the discretion of the Office of the Secretary and will depend largely on whether that Office believes that a narrowing of the request could put the request on a faster track. The regulation further provides that requesters who believe that their requests qualify for the fastest tracks and who wish to be notified if the Office of the Secretary disagrees may so indicate in the request. If practicable, the Office of the Secretary may also work with such requesters to limit their requests to qualify for a faster track.

### D. Time Limit for Responding to Requests

1. General: EFOIA lengthened the time within which agencies must respond to FOIA requests from ten to twenty working days. EFOIA sec. 8(b); 5 U.S.C. 552(a)(6)(A)(i). The regulations amend the Commission's current regulations to conform to the new time limit. See 16 CFR 1015.4, 1015.5(a), 1015.6(c).

2. Extension of time in unusual circumstances: Under FOIA section 552(a)(6)(B), agencies are permitted to extend the time limit for responding to a request or deciding an appeal of a denial of a request in "unusual circumstances," as defined in that section, for no more than ten working days, upon written notice to the requester. 5 U.S.C. 552(a)(6)(B). EFOIA amends this provision to permit agencies to extend the response time by notifying the requesters and providing them with an opportunity to: (1) Limit the scope of the request so that it may be timely answered; or (2) arrange with the agency an alternative time frame for processing the request. EFOIA sec. 7(b); 5 U.S.C. 552(a)(6)(B)(ii). EFOIA also provides that a requester's refusal to modify a request or arrange an alternative response time shall be considered a factor in the judicial review of an agency's failure to comply with the applicable time limits. EFOIA does not alter the definition of "unusual circumstances."

The regulations add a new paragraph (d) to 16 CFR 1015.5 to implement the amended provision.

3. Aggregation of related requests: EFOIA authorizes agencies to promulgate regulations providing for the aggregation of related requests by the same requester or a group of requesters acting in concert when the requests would, if treated as a single request, present "unusual circumstances" as

defined in 5 U.S.C. 552(a)(6)(B). EFOIA sec. 7(b); 5 U.S.C. 552(a)(6)(B)(iv). Section 1015.5(e) implements this provision. As EFOIA specifies, the regulation provides that requests will be aggregated only when the Commission "reasonably believes that such requests actually constitute a single request" and the requests "involve clearly related matters." *Id.*; 16 CFR 1015.5(e).

4. Requests for expedited processing: EFOIA requires each agency to promulgate regulations providing for the expedited processing of FOIA requests in cases of "compelling need" and in other cases determined by the agency. EFOIA sec. 8(a); 5 U.S.C. 552(a)(6)(E)(i). The statute specifies two categories of "compelling need":

(1) That a failure to obtain requested records on an expedited basis under this paragraph 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, urgency to inform the public concerning actual or alleged Federal Government activity.

5 U.S.C. 552(a)(6)(E)(v). Additionally, the statute sets forth requirements for the handling of requests for expedited processing and for the judicial review of agency denials of such requests. 5 U.S.C. 552(a)(6)(E)(ii)-(iv).

Section 1015.5(f) implements the expedited processing requirements of EFOIA. The Commission emphasizes that it intends to strictly adhere to Congress' express intent that the specified criteria for compelling need "be narrowly applied." Expedited processing will be granted only in those cases meeting the specific statutory requirements. H.R. Rep. 795, 104th Cong., 2d Sess. 26 (1996)(hereafter "House Report"). We expect that such cases will be rare. As the legislative history states, "the expedited process procedure is intended to be limited to circumstances in which a delay in obtaining information can reasonably be foreseen to cause a significant adverse consequence to a recognized interest." *Id.*

A requester seeking expedited processing under the "imminent threat" category of the "compelling need" definition must show that: (1) The failure to obtain the information expeditiously threatens the life or safety of an individual; and (2) the threat is "imminent." That an individual or his or her attorney needs information for an approaching litigation deadline is not a "compelling need" under this provision.

A requester seeking expedited processing under the second, "urgency

to inform," category must show that: (1) he or she is "primarily engaged in disseminating information;" (2) there is an "urgency to inform the public" about the information requested; and (3) the information relates to an "actual or alleged Federal government activity."

To meet the first "urgency to inform" criterion, the requester must show that his or her principal occupation is disseminating information to the public. As the legislative history makes clear, "[a] requester who only incidentally engages in information dissemination, besides other activities, would not satisfy this requirement." *Id.*

To meet the second "urgency to inform" criterion, the requester must show more than a general interest in the "public's right to know." See *id.* Rather, as explained in the legislative history, a requester must show that a delay in the release of the requested information would "compromise a significant recognized interest," and that the requested information "pertain[s] to a matter of current exigency to the American public." *Id.* (emphasis added). A reporter seeking expedited access to information would have to show, for example, that processing the requested information under the regular time limits would harm the public's ability to assess the subject governmental activity. (See also the discussion of the comments, below, for a further explanation of this criterion.)

The final "urgency to inform" criterion makes clear that the information must relate to the activities of the Commission and its staff. A request for expedited processing could thus be considered for information relating, for example, to a Commission decision. The Office of the Secretary generally would not, however, grant a request for expedited processing of information the Commission has collected regarding incidents involving specific consumer products.

EFOIA also authorizes agencies to expand the categories of requests qualifying for expedited processing beyond the two specified in the statute. EFOIA sec. 8(a); 5 U.S.C. 552(a)(6)(E)(i)(II). The Commission has determined that no further categories are currently necessary or appropriate. As the legislative history explains, "Given the finite resources generally available for fulfilling FOIA requests, unduly generous use of the expedited processing procedure would unfairly disadvantage other requestors who do not qualify for its treatment." House Report at 26.

Section 1015.5(f)(5) states that the Secretary will process requests granted expedited processing "as soon as

practicable." See EFOIA sec. 8(a); 5 U.S.C. 552(a)(6)(E)(iii). Pursuant to this requirement, the Office of the Secretary will give priority to such requests.

5. Time limits and section 6(b) of the Consumer Product Safety Act: Pursuant to section 6(b) of the Consumer Product Safety Act (15 U.S.C. 2055(b)), prior to the release of information that identifies a manufacturer or private labeler, the Commission must "take reasonable steps to assure \* \* \* that [the information] is accurate, and that [its] disclosure is fair in the circumstances and reasonably related to effectuating the purposes of the [Consumer Product Safety Act]." Section 6(b) requires that the Commission notify identified manufacturers and private labelers that it intends to disclose information at least 30 days prior to the disclosure. 15 U.S.C. 2055(b)(1). The manufacturer or private labeler may then submit comments regarding the disclosure of the information to the Commission. *Id.* If the Commission, after reviewing the comments, decides to release the information over the accuracy objections of the manufacturer or private labeler, it must so notify the firm at least 10 days prior to the release. 15 U.S.C. 2055(b)(2).

The Supreme Court, in *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102 (1980), ruled that the Commission must follow the requirements of section 6(b) prior to the release of information in response to a FOIA request. As a result, it is frequently impossible for the Commission to comply with FOIA time limits when information responsive to a request identifies a manufacturer or private labeler. When the Office of the Secretary receives a request for information that requires section 6(b) review, it routinely notifies the requester that the response will be delayed. Section 1015.5(g) is intended to assure that requesters are aware of the requirements of section 6(b) and of the Commission's section 6(b) regulations at 16 CFR Part 1101.

#### *E. Estimates of the Volume of Materials Denied*

EFOIA requires that agency responses denying information include an estimate of the volume of any responsive documents the agency is withholding. EFOIA sec. 8(c); 5 U.S.C. 552(a)(6)(F). Additionally, EFOIA requires that when an agency withholds only a portion of a record, the response shall indicate the amount of information deleted on the released record, where possible at the place of the deletion. EFOIA sec. 9; 5 U.S.C. 552(b)(9). Section 1015.6 includes a new subparagraph

(b)(3) to implement these new requirements.

#### F. Fees

Sections 1015.9 (e)(5) and (g)(1) amend the current regulation on fees the agency charges for the production of documents to reflect current Commission practices. Current section 1015.9(e)(5) sets forth the amount charged for computerized records that the Commission retrieves from an offsite central processing system. Currently, the majority of computer printouts are made at the Commission's offices, and the specified calculation is inapplicable. Section 1015.9(e)(5) amends the regulation to specify a charge of ten cents per page for computer printouts generated at the Commission.

Section 1015.9(g)(1) currently states that interest will be charged on fees owed "on the 31st day following the day on which the billing was sent." (Emphasis added.) Section 1015.9(g)(1) amends the regulation to provide that interest will instead be calculated based on the day the requester receives the bill, as is the current Commission practice.

#### G. Annual Report to Congress

The current Commission regulations describe the information the Commission submits to Congress annually regarding the Commission's processing of FOIA requests. 16 CFR 1015.10. EFOIA amended the FOIA provisions regarding reporting in several ways, including the timing of reports and the information to be reported. EFOIA sec. 10; 5 U.S.C. 552(e). The regulations amend section 1015.10 to conform to the EFOIA reporting requirements.

#### Comments

The Commission received three comments in response to the proposed rule, two from trade associations of appliance manufacturers—the Association of Home Appliance Manufacturers (AHAM) and the Gas Appliance Manufacturers Association (GAMA)—and one from a journalists' trade association—The Reporters Committee for Freedom of the Press ("Reporters Committee"). The appliance manufacturers commented about the effect of the EFOIA amendments on the Commission's regulations interpreting section 6(b) of the CPSA. The Reporters Committee objected to certain of the provisions for expedited processing in section 1015.5(f). The Reporters Committee also objected to the absence of a discussion in the regulations of access to electronic records.

#### A. EFOIA and the Commission's Section 6(b) Regulations

Section 1015.2(c) states: "The [Commission] will maintain an 'electronic reading room' on the World-Wide Web for those records which are required by 5 U.S.C. 552(a)(2) to be available by 'computer telecommunications.'" The preamble to the proposed rule explained that, pursuant to 5 U.S.C. 552(a)(2)(D), those records would include records that the Commission releases under FOIA and become, or are likely to become, the subject of subsequent FOIA requests. 62 FR at 24615. Neither the regulation nor the preamble further explained what records the Commission would make available on the Web.

AHAM and GAMA urged that the new regulations include a provision specifically addressing the effect of the EFOIA electronic reading room requirement on documents that are subject to review under section 6(b) of the CPSA. 15 U.S.C. 2055(b). As stated above, section 6(b) provides manufacturers the opportunity to comment on the disclosure of documents that identify them. AHAM and GAMA noted that pursuant to 16 CFR 1101.31(d), the Commission provides manufacturers the opportunity to request renotification each time the Commission receives a FOIA request for the documents. AHAM and GAMA asked that the regulations state that those documents for which manufacturers request renotification will not be placed in the electronic reading room.

The Commission does not currently intend to place in either the traditional or electronic reading rooms records that are described in 5 U.S.C. 552(a)(2)(D), if the identified manufacturer has requested renotification. We do intend to make available in the reading rooms a list of those files that would be in the reading rooms pursuant to 5 U.S.C. 552(a)(2)(D), but for the manufacturer's request for renotification.

We do not, however, agree that the regulation should be changed in the final rule to make this policy explicit. Section 1015.2(c) simply states that the Commission will comply with the electronic reading room provision of EFOIA. It does not—and we believe need not—interpret the application of EFOIA to specific Commission records.

#### B. Expedited Processing

As explained above, EFOIA requires agencies to promulgate regulations providing for the expedited processing of requests when the requester demonstrates a "compelling need" for

the information. 5 U.S.C. 552(a)(6)(E). "Compelling need" is defined to include two categories of requests: (1) Where information is necessary to prevent an "imminent threat;" and (2) where the requester shows an "urgency to inform the public" about the information. 5 U.S.C. 552(a)(6)(E)(v).

Section 1015.5(f) sets forth the criteria and process for expedited processing. It repeats, without interpretation, the requirements of 5 U.S.C. 552(a)(6)(E). The preamble to the proposed rule elaborated upon the definition of "compelling need" with respect to the "urgency to inform" prong. 62 FR at 24,616. The Reporters Committee objected to certain of these statements and to the certification requirement of 16 CFR 1015.5(f)(2). As explained below, we decline to modify the regulation in response to these comments.

#### 1. Expedited Processing and "Compelling Need"

The Reporters Committee argues that the statement in the preamble to the proposed rule that expedited processing will be granted only in "truly extraordinary circumstances" is too restrictive. 62 FR at 24616. We do not believe that this statement mischaracterized Congress' intent that expedited review be "narrowly applied." H.R. Rep. 795, 104th Cong., 2d Sess. 26 (1996). However, we have modified the preamble and do not now employ the phrase to which objection was made. The Commission will grant expedited review to all requests that meet the strict statutory requirements for "compelling need."

#### 2. The "Urgency to Inform" Criteria

The Reporters Committee objects to the preamble descriptions of the showing necessary to support each of the three criterion necessary to meet the "urgency to inform" prong of the "compelling need" definition:

a. "Primarily engaged in disseminating information". The preamble noted that the first "urgency to inform" criterion—that the requester is "primarily engaged in disseminating information"—requires a showing that the requester's principal occupation is disseminating information to the public. 62 FR at 24616. The Reporters Committee argues that this provision requires only that the requester be primarily engaged in disseminating the information responsive to the particular request, not that the requester be so engaged generally.

We do not believe that this is a reasonable interpretation of the statute, as elaborated by the legislative history

quoted in the preamble. Although the Commission does not intend, as the Reporters Committee states, to "spend time deciding what percentage of a requester's occupational workload is devoted to the dissemination of information," we do intend to limit expedited review to requests from media representatives and others whose "main activity" is to disseminate information. See H.R. Rep. 795, 104th Cong., 2d Sess. 26 (1996) ("The standard of 'primarily engaged' requires that information dissemination be the main activity of the requester, although it need not be their sole occupation.").

b. *"Urgency to inform the public"*. The Reporters Committee objects that the preamble interpreted the term "urgency to inform" too narrowly, to include only information "currently of significant interest to the public." See 62 FR at 24616. It argues that there may be an "urgency to inform" the public about information not yet publicly known. We agree that there could be information not yet publicly known that is, in the words of the House Report, of "current exigency to the American public," in that failure to disseminate the information would "compromise a significant recognized interest." See H.R. Rep. at 26. Accordingly, we have modified the discussion of the "urgency to inform" criterion in the preamble to this final rule. (See section D.4 of the discussion of the New Provisions, above.) We emphasize, however, that a generalized interest in the public's right to know would be an insufficient showing of "compelling need."

c. *"Actual or alleged Federal Government activity"*. The preamble to the proposed rule explained that only information that relates to the activities of the Commission and its staff would meet the third of the "urgency to inform" criteria. 62 FR at 24616. The preamble noted that the Office of the Secretary generally would not grant a request for expedited processing of information the Commission has collected regarding incidents involving specific consumer products. *Id.* The Reporters Committee objects, arguing that because it is the mission of the Commission to collect such information, it cannot be excluded from expedited review.

The preamble stated that such information generally would not qualify for expedited processing, a position to which we adhere. The Commission's files include thousands of consumer complaints and investigation reports regarding incidents involving consumer products that the Commission staff has not analyzed or otherwise pursued. Although the collection of such

information is a Commission activity, we do not believe that the collection alone makes the reports subject to expedited processing as information "concerning actual or alleged Federal Government activity." This is not to suggest that the Office of the Secretary would never grant expedited processing of a request for this information.

### 3. The Certification Requirement

Finally, the Reporters Committee argues that the requirement of section 1015.5(f)(2) that requesters submit a certified statement demonstrating "compelling need" is "absurd," "completely unexpected," and designed solely to "serve the bureaucratic interests of the agency." However, this requirement is in the statute. Section 8(a) of EFOIA (codified at 5 U.S.C. 552(a)(6)(E)(vi)) states:

A demonstration of compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief.

### C. Access to Records in Electronic Format

The Reporters Committee objects to the absence in the proposed regulations of discussion of compliance with the EFOIA provisions regarding access to records in electronic format. Although the Commission intends to comply with the provisions of EFOIA, the proposed regulations amend the Commission's current FOIA regulations only where the statute specifically required or authorized new regulations (for example, the regulations regarding expedited processing and the aggregation of requests) or where the current regulations conflict with EFOIA (for example, the time limit for responding to requests). The Commission does not believe it is either necessary or advisable to further amend the FOIA regulations at this time.

### Effective Date

The amendments become effective October 2, 1997.

### Impact on Small Business

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that these amendments will not have a significant economic impact upon a substantial number of small entities.

### Environmental Considerations

These amendments do not fall within any of the categories of Commission activities described in 16 CFR 1021.5(b) that have the potential for producing

environmental effects and which, therefore, require environmental assessments, and, in some cases, environmental impact statements. The Commission does not believe that the amendments contain any unusual aspects that may produce effects on the human environment, nor can the Commission foresee any circumstances in which the amendments may produce such effects. For this reason, neither an environmental assessment nor an environmental impact statement is required.

### Preemption

In accordance with Executive Order 12988 (February 5, 1996), the Commission states that these amendments have no preemptive effect.

### Federalism Assessment

These amendments have been evaluated for federalism implications in accordance with Executive Order 12612, and they raise no substantial federalism concerns.

### List of Subjects in 16 CFR Part 1015

Administrative practice and procedure, Consumer protection, Disclosure of information, Freedom of information.

In accordance with the provisions of 5 U.S.C. 553 and under the authority of the Consumer Product Safety Act, 15 U.S.C. 2051 *et seq.*, the Commission amends Part 1015 of Title 16, Chapter II, of the Code of Federal Regulations as follows:

### PART 1015—PROCEDURES FOR DISCLOSURE OR PRODUCTION OF INFORMATION UNDER THE FREEDOM OF INFORMATION ACT

1. The authority citation for part 1015 is revised to read as follows:

**Authority:** 15 U.S.C. 2051–2084; 15 U.S.C. 1261–1278; 15 U.S.C. 1471–1476; 15 U.S.C. 1211–1214; 15 U.S.C. 1191–1204; 5 U.S.C. 552.

2. Section 1015.1 is amended by revising the second and third sentences of paragraph (a) as follows:

#### § 1015.1 Purpose and scope.

(a) \* \* \* Official records of the Consumer Product Safety Commission consist of all documentary material maintained by the Commission in any format, including an electronic format. These records include those maintained in connection with the Commission's responsibilities and functions under the Consumer Product Safety Act, as well as those responsibilities and functions transferred to the Commission under the Federal Hazardous Substances Act,

Poison Prevention Packaging Act of 1970, Refrigerator Safety Act, and Flammable Fabrics Act, and those maintained under any other authorized activity \* \* \*

3. Section 1015.2 is amended by revising paragraph (a) and adding paragraph (c) as follows:

§ 1015.2 Public reference facilities.

(a) The Consumer Product Safety Commission will maintain in a public reference room or area the materials relating to the Consumer Product Safety Commission that are required by 5 U.S.C. 552(a)(2) and 552(a)(5) to be made available for public inspection and copying. The principal location will be in the Office of the Secretary of the Commission. The address of this office is: Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814.

(c) The Consumer Product Safety Commission will maintain an "electronic reading room" on the World-Wide Web for those records that are required by 5 U.S.C. 552(a)(2) to be available by "computer telecommunications."

4. Section 1015.3 is amended by adding a new paragraph (e) as follows:

§ 1015.3 Requests for records and copies.

(e) The Consumer Product Safety Commission uses a multitask system to process requests under the Freedom of Information Act that is based on the amount of work and/or time involved in processing requests. Requests for records are processed in the order they are received within each track. Upon receipt of a request for records, the Secretary or delegate of the Secretary will determine which track is appropriate for the request. The Secretary or delegate of the Secretary may contact requesters whose requests do not appear to qualify for the fastest tracks and provide such requesters the opportunity to limit their requests so as to qualify for a faster track. Requesters who believe that their requests qualify for the fastest tracks and who wish to be notified if the Secretary or delegate of the Secretary disagrees may so indicate in the request and, where appropriate and feasible, will also be given an opportunity to limit their requests.

5. Section 1015.4 is amended by revising the last sentence to read as follows:

§ 1015.4 Responses to requests for records; responsibility.

\* \* \* If no response is made by the Commission within twenty working days, or any extension thereof, the requester and the Commission may take the action specified in § 1015.7(e).

6. Section 1015.5 is amended by revising the heading and the first sentence of paragraph (a), changing the phrase "Chairman of the Commission" to "General Counsel of the Commission" in paragraph (b), and adding new paragraphs (d), (e), (f), and (g) as follows:

§ 1015.5 Time limitation on responses to requests for records and requests for expedited processing.

(a) The Secretary or delegate of the Secretary shall respond to all written requests for records within twenty (20) working days (excepting Saturdays, Sundays, and legal public holidays). \* \* \*

(d) If the Secretary at the initial stage or the General Counsel at the appellate stage determines that an extension of time greater than ten (10) working days is necessary to respond to a request satisfying the "unusual circumstances" specified in paragraph (b) of this section, the Secretary or the General Counsel shall so notify the requester and give the requester the opportunity to:

(1) Limit the scope of the request so that it may be processed within the time limit prescribed in paragraph (b); or

(2) Arrange with the Secretary or the General Counsel an alternative time frame for processing the request or a modified request.

(e) The Secretary or delegate of the Secretary may aggregate and process as a single request requests by the same requester, or a group of requesters acting in concert, if the Secretary or delegate reasonably believes that the requests actually constitute a single request which would otherwise satisfy the unusual circumstances specified in paragraph (b) of this section, and the requests involve clearly related matters.

(f) The Secretary or delegate of the Secretary will provide expedited processing of requests in cases where the requester demonstrates a compelling need for such processing.

(1) The term "compelling need" means:

(i) That 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

(ii) With respect to a request made by a person primarily engaged in

disseminating information, that there is an urgency to inform the public concerning actual or alleged Federal Government activity.

(2) Requesters for expedited processing must include in their requests a statement setting forth the basis for the claim that a "compelling need" exists for the requested information, certified by the requester to be true and correct to the best of his or her knowledge and belief.

(3) The Secretary or delegate of the Secretary will determine whether to grant a request for expedited processing and will notify the requester of such determination within ten (10) days of receipt of the request.

(4) Denials of requests for expedited processing may be appealed to the Office of the General Counsel as set forth in § 1015.7 of this part. The General Counsel will expeditiously determine any such appeal.

(5) The Secretary or delegate of the Secretary will process as soon as practicable the documents responsive to a request for which expedited processing is granted.

(g) The Secretary may be unable to comply with the time limits set forth in this § 1015.5 when disclosure of documents responsive to a request under this part is subject to the requirements of section 6(b) of the Consumer Product Safety Act, 15 U.S.C. 2055(b), and the regulations implementing that section, 16 CFR part 1101. The Secretary or delegate of the Secretary will notify requesters whose requests will be delayed for this reason.

7. Section 1015.6 is amended by redesignating paragraph (b)(3) as (b)(4), adding a new paragraph (b)(3), and revising the first sentence of paragraph (c) as follows:

§ 1015.6 Responses: Form and content.

(3) An estimation of the volume of requested material withheld. When only a portion or portions of a document are withheld, the amount of information deleted shall be indicated on the released portion(s) of the record. When technically feasible, the indication of the amount of material withheld will appear at the place in the document where any deletion is made. Neither an estimation of the volume of requested material nor an indication of the amount of information deleted shall be included in a response if doing so would harm an interest protected by the exemption in 5 U.S.C. 552(b) pursuant to which the material is withheld.

(c) If no response is made within twenty (20) working days or any extension thereof, the requester can consider his or her administrative remedies exhausted and seek judicial relief in a United States District Court as specified in 5 U.S.C. 552(a)(4)(B). \* \* \*

8. Section 1015.9 is amended by revising paragraphs (e)(5) and (g)(1) to read as follows:

**§ 1015.9 Fees for production of records.**

\* \* \* \* \*

(e) \* \* \*

(5) Computerized records: \$0.10 per page of computer printouts or, for central processing, \$0.32 per second of central processing unit (CPU) time; for printer, \$10.00 per 1,000 lines; and for computer magnetic tapes or discs, direct costs.

\* \* \* \* \*

(g) \* \* \*

(1) Interest will be charged on amounts billed, starting on the 31st day following the day on which the requester received the bill. Interest will be at the rate prescribed in 31 U.S.C. 3717.

\* \* \* \* \*

9. Section 1015.10 is amended by revising the introductory text and paragraphs (b) through (g) as follows:

**§ 1015.10 Commission report of actions to Congress.**

On or before February 1 of each year, the Commission shall submit a report of its activities with regard to freedom of information requests during the preceding fiscal year to the Attorney General of the United States. This report shall include:

\* \* \* \* \*

(b)(1) The number of appeals made by persons under such provisions, the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; and

(2) A complete list of all statutes that the Commission relies upon to withhold information under such provisions, a description of whether a court has upheld the decision of the Commission to withhold information under each such statute, and a concise description of the scope of any information withheld.

(c) The number of requests for records pending before the Commission as of September 30 of the preceding year, and the median number of days that such requests had been pending before the Commission as of that date.

(d) The number of requests for records received by the Commission and the number of requests which the Commission processed.

(e) The median number of days taken by the Commission to process different types of requests.

(f) The total amount of fees collected by the Commission for processing requests.

(g) The number of full-time staff of the Commission devoted to processing requests for records under such provisions, and the total amount expended by the Commission for processing such requests.

Dated: August 26, 1997.

**Sadye E. Dunn,**

*Secretary, Consumer Product Safety Commission.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 50, 56, 312, 314, 601, 812, and 814**

[Docket No. 97N-0342]

**Implementation of Emergency Research Informed Consent Waiver Rule; Public Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of a public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on the implementation of a final rule that defined conditions for an exception to the normal requirements for obtaining informed consent from persons participating as subjects in research. FDA is holding the public meeting because some parties interested in research conducted under the final rule have expressed to FDA a need for additional information on acceptable implementation procedures. The purpose of this public meeting is to provide an open discussion of the issues involved in implementing the requirements of the rule.

**DATES:** The public meeting will be held on September 29 and 30, 1997. On September 29, 1997, the meeting will be from 9:30 a.m. to approximately 5:30 p.m. On September 30, 1997, the meeting will be from 8 a.m. to approximately 11:45 a.m. Registration is recommended by September 19, 1997. Opportunity for public participation will be provided during both days of the meeting. Written comments will be accepted until October 31, 1997.

**ADDRESSES:** The public meeting will be held at the Bethesda Holiday Inn, 8120

Wisconsin Ave., Bethesda, MD. Written information and comments related to the meeting should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. **FOR FURTHER INFORMATION CONTACT:** Glen D. Drew, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, rm. 15-22, Rockville, MD 20857, 301-443-1382, FAX 301-443-0232.

**SUPPLEMENTARY INFORMATION:** The purpose of this public meeting is to provide an open discussion of the issues involved in implementing the requirements of the final rule. Participants will be encouraged to discuss their perspectives on implementation of the final rule. Members of the public are encouraged to attend and provide comments during periods of open discussion and to provide written comments to the docket. Written comments by interested parties are encouraged, whether or not they are able to attend the public meeting.

The requirement for obtaining the informed consent of persons participating in clinical research as research subjects has long been recognized, and has been included in FDA's regulations since the early 1960's. The current regulations on informed consent part 50 (21 CFR part 50) and institutional review boards (IRB's) (21 CFR part 56) were finalized in 1981. Those regulations require that clinical researchers obtain informed consent from all subjects, with narrowly limited exceptions.

As the field of emergency medicine evolved, treatments were developed for conditions such as head trauma, stroke, and heart attack that were previously considered hopeless. The need for the development of treatment methods where only unsatisfactory methods existed and to determine the effectiveness of new treatments was recognized in the medical community. The importance of obtaining informed consent as an integral part of the protection of human subjects was also recognized. The Subcommittee on Regulation, Business Opportunities, and Technology of the House Committee on Small Business, held a hearing on May 23, 1994, that addressed problems encountered in securing informed consent of subjects in clinical trails of investigational drugs and medical devices. A coalition of acute resuscitation and critical care researchers held an October 1994