(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.

[FR Doc. 97–23242 Filed 8–29–97; 8:45 am]

BILLING CODE 6355–01–U

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

conference on the issues involved. In January 1995, FDA and the National Institutes of Health cosponsored a public forum on informed consent in clinical research conducted in emergency circumstances. In the **Federal Register** of September 21, 1995 (60 FR 49086), FDA proposed to amend its regulations to provide an exception to informed consent for research of emergency treatment for persons with acute and unpredictable life-threatening illnesses. After analysis of over 90 comments, in the **Federal Register** October 2, 1996 (61 FR 51498), FDA published the final rule (§ 50.24) that is the subject of this public meeting. The Department of Health and Human Services simultaneously published (61 FR 51531, October 2, 1996) a functionally equivalent waiver of its human subject protection regulations (45 CFR part 46).

The exception to the normal requirements for obtaining informed consent (61 FR 51531) is narrow in scope and available for research conducted in emergency circumstances on treatments for life-threatening conditions. The exception requires additional protections beyond those provided for human research subjects in other research.

While § 50.24 provides specific requirements for use of the exception to informed consent, FDA recognized that local conditions vary throughout the Nation, and placed considerable discretion and responsibility in the IRB's that will review proposed studies, the clinical investigators who will conduct the studies, and the sponsors who will initiate the studies and utilize the results. Questions have arisen as to the appropriate methods to satisfy the regulatory requirements imposed for use of the exception.

At the public meeting, participants will examine the methods of providing the additional protections required when utilizing the exception to informed consent. Presentations and discussions will address the specific measures required. Participants will be provided opportunities to share their views and information regarding protocol design, study conduct, and experiences of clinical research conducted or planned under the exception to informed consent.

On September 29, 1997, the meeting will open with discussions describing how the final rule was developed, what FDA expects to receive from sponsors, and how to determine whether clinical equipoise exists between standard therapy and an investigational procedure. Representatives of a study sponsor will describe how that study has been implemented at multiple study sites. A panel of experts will discuss issues related to consultation with representatives of the community where the research will be conducted and from which subjects will be drawn, if different, and disclosure of the research to the community. A session of open discussion will provide an opportunity for audience participation. A second panel of experts will discuss issues related to procedures for seeking consent from a subject's legal representative, and documenting the attempts to obtain consent. A session of open discussion will follow.

On September 30, 1997, the meeting will open with presentations describing the function and operation of data safety monitoring boards that are required for studies under the final rule, as well as the other requirements of the final rule. A representative of a study sponsor will describe the preparation for and coordination of a multi-site study. A panel of experts will discuss the circumstances in which it is appropriate to use the final rule, and how the different parties involved should interact with each other to produce a useful study. A session of open discussion will follow and then the meeting will conclude.

All sessions of the meeting are open to the public; however, open seating is limited to 300. Those persons interested in attending should submit registration information, including name, organization name, address, telephone and fax numbers to the contact listed in this document. There is no registration fee for this public meeting, but advanced registration is recommended, as preregistrants will have preference if seating capacity is exceeded. Interested parties are encouraged to register early because space is limited.

Interested persons may, on or before October 31, 1997, submit to the Dockets Management Branch (address above) written comments regarding the workshop. 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. Additional information as well as a registration form is also available at FDA's website at http.//www.fda.gov.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23123 Filed 8–29–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD040–3018a; FRL–5881–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compound Emissions From Sheet-Fed and Web Lithographic Printing and Paper Coatings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) revisions submitted by the State of Maryland on July 11, 1995. These revisions establish volatile organic compound (VOC) emission reduction requirements for sheet-fed and web lithographic printing operations, and paper, fabric, vinyl, and other plastic coating operations throughout the State of Maryland under COMAR 26.11.19 Volatile Organic Compounds from Specific Processes. EPA is also approving the administrative changes to Maryland's regulations for VOC emissions from specific processes. The intended effect of this action is to approve these provisions into the Maryland SIP, in accordance with the SIP submittal and revision provisions of the Clean Air Act (the Act). This action is being taken under section 110 of the Act.

EFFECTIVE DATE: This final rule is effective November 3, 1997 unless by October 2, 1997, adverse or critical comments are received. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments may be mailed to David L. Arnold, Chief, Ozone/CO and Mobile Sources Section, Mailcode 3AT21, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107 and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Carolyn M. Donahue, (215) 566–2095, at the EPA Region III office address listed above, or via e-mail at donahue.carolyn@epamail.epa.gov. While information may be requested via e-mail, comments must be submitted in writing to the above Region III address.