issued as a Level 1 guidance consistent with GGP's.

### III. Electronic Access

In order to receive the ''Intraocular Lens Guidance Document'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (834) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH Home Page includes the ''Intraocular Lens Guidance Document,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Intraocular Lens Guidance Document'' will be available at ''http://www.fda.gov/cdrh/ode/iol-guidance.pds''.

### IV. Comments

Interested persons may, on or before January 12, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 29, 1999.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 99–26719 Filed 10–13–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 99D–4052]**

## Medical Devices; Draft Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater.'' This draft guidance document discusses issues that should be addressed in a premarket notification (510(k)) application submitted to establish the substantial equivalence of a proposed processed human dura mater device to other similar products in commercial distribution. This draft guidance document also provides a brief background on processed human dura mater regulation. It is intended to replace the guidance document ''Guide for 510(k) Review of Processed Human Dura Mater'' dated June 26, 1990. This guidance incorporates recommendations from the October 6, 1997, and April 16, 1998, meetings of the FDA Transmissible Spongiform Encephalopathies Advisory Committee (FDA TSE Advisory Committee), which discussed the manufacture and clinical use of processed human dura mater products.

**DATES:** Written comments concerning this draft guidance must be submitted by January 12, 2000.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

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

**FOR FURTHER INFORMATION CONTACT:** Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Processed human dura mater was in commercial distribution before the enactment of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. While a classification recommendation was discussed at the February 2, 1990, meeting of the Neurological Devices Advisory Panel, product classification was not finalized. In March 1997, the World Health Organization (WHO) recommended (based on concerns of Creutzfeldt Jakob Disease (CJD) transmission that processed human dura mater no longer be used, especially in neurosurgery, unless no alternative was available. At the same time, the Japanese Health and Welfare Ministry banned the use of processed human dura mater in brain surgery in Japan.

Because FDA established safeguards and guidelines in 1990 to minimize the possibility of CJD transmission by processed human dura mater implantation, and because there were no confirmed cases of CJD transmission related to the use of processed human dura mater in the United States as of March 1997, FDA did not restrict the distribution of processed human dura mater in the United States. However, the decision was made to hold public meetings of the FDA TSE Advisory Committee to reevaluate the safety of processed human dura mater grafts with respect to surgical use and CJD transmission.

On October 6, 1997, the FDA TSE Advisory Committee met to consider information provided by FDA, industry, CDC, National Institutes of Health (NIH), the neurology medical community, and other internationally recognized experts concerning the clinical benefits and risks of CJD transmission associated with processed human dura mater grafts. At the conclusion of this meeting, the committee recommended unanimously that neurosurgeons should avoid the use of processed human dura mater whenever possible. The committee concluded, however, that the final decision to use processed human dura mater should be left to the discretion of the treating neurosurgeon, as long as the human dura mater is procured and processed following certain safety measures.

To improve the safety of processed human dura mater, and based upon the committee's recommendations, on March 6, 1998, FDA sent letters to providers of processed human dura mater requesting that they implement specific measures that may be beyond their standard operating procedures. On April 16, 1998, FDA presented to the FDA TSE Advisory Committee proposed revisions to the committee recommendations from the October 6, 1997, meeting. These revisions took into consideration the responses from the processed human dura mater suppliers to the FDA letter of March 6, 1998. This guidance was prepared to replace the existing FDA guidance ''Guide for 510(k) Review of Processed Human Dura Mater'' dated June 26, 1990, and to incorporate the recommendations received from the FDA TSE Advisory Committee and the responses from manufacturers.

## II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the preparation of a premarket notification for processed human dura mater. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's. Public comment prior to implementation of this guidance document is not required because the guidance is needed to address a significant public health issue. However, the agency did solicit input from the FDA TSE Advisory Committee and processed human dura mater suppliers provided comments on FDA's approach in response to FDA's March 6, 1998, letter.

## III. Electronic Access

In order to receive the ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (054) followed by the pound sign(#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the web. Updated on a regular basis, the CDRH home page includes ''Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance for the Preparation of a Premarket Notification Application for Process Human Dura Mater'' will be available at http://www.fda.gov/cdrh/ode/054.pdf.

## IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1999.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 99–26720 Filed 10–13–99; 8:45 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[Document Identifier: HCFA–R–0262]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Adjusted Community Rate Proposal (ACRP) M+C Plan Benefit Package and Supporting Regulations in 42 CFR 417.401, 422.1–.10, 422.50–.80, 422.100–.132, 422.300–.312, 422.400–.404, and 422.560–.622; *Form No.:* HCFA–R–0262 (OMB #0938–0763); *Use:* The plan year 2000 pilot collection effort will be used to verify that the information collection instrument will produce the data HCFA needs to approve M+C plans in the future. Respondents include any M+C organization that intends to offer an M+C plan in calendar year 2000.

This collection will also allow the Agency to provide a totally automated submission and review capability, replace text with data format, establish a standard set of benefit descriptions/definitions, provide a framework to describe benefits, reduce variation in benefit descriptions, collect benefit information and Medicare Compare data with a single instrument, and eliminate the need to validate Medicare Compare data.; *Frequency:* Annual; *Affected Public:* Business or other for-profit, and Not-for-profit institution.; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and