ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Program Narrative Objective Work Plan (OWP):	650	1	28	18,200

Estimated Total Annual Burden Hours: 18,200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestion submitted within 60 days of this publication.

Dated: October 7, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–26728 Filed 10–13–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4054]

Draft Guidance for Industry on Intraocular Lens; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Intraocular Lens Guidance Document.'' This draft guidance is not final nor is it in effect at this time. This draft guidance describes preclinical and clinical requirements that may be used in support of investigational device exemptions, premarket approval applications, and product development protocols. This draft guidance describes for industry and FDA reviewers the type of information needed to support investigational and marketing applications for intraocular lenses.

DATES: Written comments concerning this guidance must be received by January 12, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Intraocular Lens Guidance Document'' 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. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to this draft guidance.

FOR FURTHER INFORMATION CONTACT: Donna R. Lochner, Center for Devices and Radiological Health (HFZ–463), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Intracular Lens Guidance Document.'' This draft guidance provides detailed information about the type of preclinical testing needed to support both a clinical investigation and marketing applications for new intraocular lenses and modifications to intraocular lenses. This draft guidance also provides the basic principles that should be applied in the conduct of a clinical study for new or modified intraocular lenses. Earlier revisions of this draft guidance have been discussed in numerous forums since April of 1997, and industry, clinicians, and other interested parties have participated. These forums have included at least three Ophthalmic Device Panel meetings at which this draft guidance, or parts of the guidance, have been discussed. These Panel discussions began before 1997, and most recently they occurred in October 1997. Both written and verbal comments have been received and discussed thoroughly in these forums.

Although this draft guidance, to a large extent, describes review elements that have been in existence since almost the inception of FDA's review of intraocular lenses, it has been refined and improved through the interactive discussions with the industry, clinicians, panel members, and other interested parties. FDA has made available to all interested parties a summary of all written comments received, and on each version of the guidance FDA has noted the changes from the previous version. This information is available for this most recent release and for previous revisions. Interested persons may obtain this information through the contact person at the address and phone number given above.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on submissions for intraocular lenses. 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 requirements of 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 guidance document is

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.