

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 12-17-03
Publication Date 12-18-03
Certifier D. Hawkins

[Docket No. 2002D-0371]

Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Human Dura Mater." This guidance document describes a means by which human dura mater may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify this device type into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Human Dura Mater" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

In the **Federal Register** of October 22, 2002 (67 FR 64835), FDA published a proposed rule to classify human dura mater into class II (special controls). FDA identified the draft guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA” as the special control, in conjunction with general controls, that is capable of providing reasonable assurance of safety and effectiveness for this device.

FDA invited interested persons to comment on the draft guidance by January 21, 2003. FDA received one comment that informed the agency of research findings concerning Creutzfeldt-Jakob Disease. The comment did not express any opinion on the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on the human dura mater device. 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 and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA)(44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E; OMB Control No. 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB Control No. 0910–0485.

IV. Comments

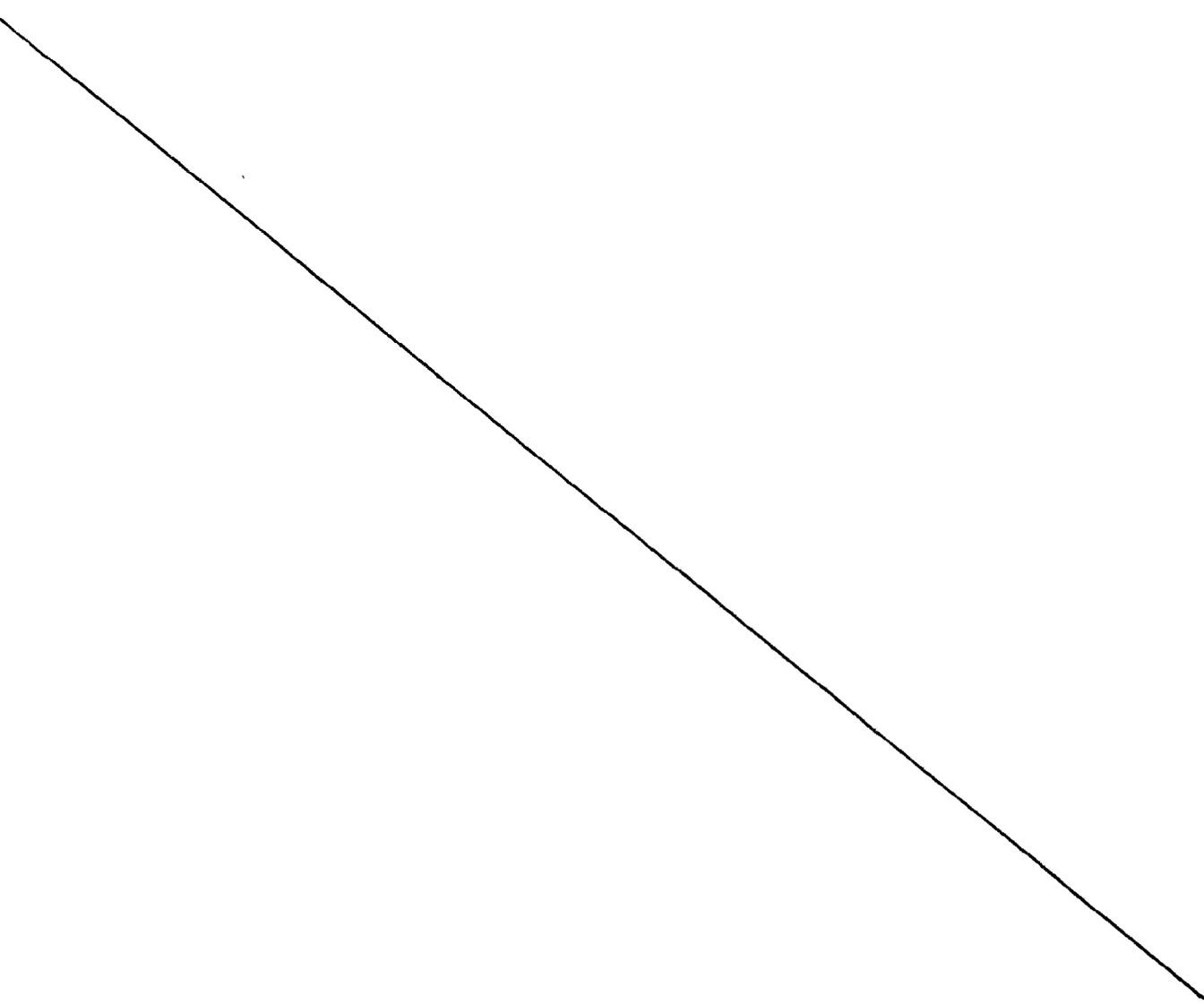
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive a copy of “Class II Special Controls Guidance Document: Human Dura Mater” by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (054) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to

a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.



Dated: 12/5/03
December 5, 2003.

ch0338

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TRUE
COPY OF THE ORIGINAL

Dawn P. Hankins