

ADVISORY COMMITTEE	NUMBER
Dermatologic and Ophthalmic Drugs Advisory Committee .....	3014512534
Drug Safety and Risk Management Advisory Committee (Drug Abuse Subcommittee) .....	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee .....	3014512536
Gastrointestinal Drugs Advisory Committee .....	3014512538
Nonprescription Drugs Advisory Committee .....	3014512541
Oncologic Drugs Advisory Committee .....	3014512542
Peripheral and Central Nervous System Drugs Advisory Committee .....	3014512543
Pharmaceutical Science, Advisory Committee for .....	3014512539
Psychopharmacologic Drugs Advisory Committee .....	3014512544
Pulmonary-Allergy Drugs Advisory Committee .....	3014512545
Reproductive Health Drugs, Advisory Committee for .....	3014512537
<b>CENTER FOR FOOD SAFETY AND APPLIED NUTRITION</b>	
Food Advisory Committee (full committee and subcommittees) .....	3014510564
Additives and Ingredients Subcommittee	
Biotechnology Subcommittee	
Contaminants and Natural Toxicants Subcommittee	
Dietary Supplements Subcommittee	
Infant Formula Subcommittee	
Nutrition Subcommittee	
<b>CENTER FOR DEVICES AND RADIOLOGICAL HEALTH</b>	
Device Good Manufacturing Practice Advisory Committee .....	3014512398
Medical Devices Advisory Committee (comprised of 18 panels) .....	N/A
Anesthesiology and Respiratory Therapy Devices Panel .....	3014512624
Circulatory System Devices Panel .....	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel .....	3014512514
Dental Products Panel .....	3014512518
Ear, Nose, and Throat Devices Panel .....	3014512522
Gastroenterology-Urology Devices Panel .....	3014512523
General and Plastic Surgery Devices Panel .....	3014512519
General Hospital and Personal Use Devices Panel .....	3014512520
Hematology and Pathology Devices Panel .....	3014512515
Immunology Devices Panel .....	3014512516
Medical Devices Dispute Resolution Panel .....	3014510232
Microbiology Devices Panel .....	3014512517
Molecular and Clinical Genetics Panel .....	3014510231
Neurological Devices Panel .....	3014512513
Obstetrics-Gynecology Devices .....	3014512524
Ophthalmic Devices Panel .....	3014512396
Orthopaedic and Rehabilitation Devices Panel .....	3014512521
Radiological Devices Panel .....	3014512526
National Mammography Quality Assurance Advisory Committee .....	3014512397
Technical Electronic Product Radiation Safety Standards Committee .....	3014512399
<b>CENTER FOR VETERINARY MEDICINE</b>	
Veterinary Medicine Advisory Committee .....	3014512548
<b>NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH</b>	
Science Advisory Board to NCTR .....	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants.	3014512560

The hotline will provide the most recent information available on upcoming advisory committee meetings, guidance for making an oral presentation during the open public hearing portion of a meeting, and procedures on obtaining copies of transcripts of advisory committee meetings. Because the hotline will communicate the most current information available about any particular advisory committee meeting, this system will provide interested parties with timely and equal access to such information. The hotline should also conserve agency resources by reducing the current volume of inquiries individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 10, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03-31157 Filed 12-17-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[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: December 5, 2003.

**Linda S. Kahan,**

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

[FR Doc. 03-31175 Filed 12-17-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Fiscal Year (FY) 2004 Funding Opportunity**

**ACTION:** Notice of funding availability for Statewide Family Network Grants.

**Authority:** Section 520 A of the Public Health Service Act, as amended and subject to the availability of funds.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS) announces the availability of FY 2004 funds for Statewide Family Network Grants. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: <http://www.grants.gov>.

For complete instructions, potential applicants must obtain a copy of the standard Infrastructure Grants Program Announcement (INF-04 PA), and the PHS 5161-1 (Rev. 7/00) application form before preparing and submitting an application. The INF-04 PA describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including Statewide Family Network Grants. Additional instructions and requirements specific to the Statewide Family Network Grants are described below.

*Funding Opportunity Title:* Statewide Family Network Grants.

*Announcement Type:* Initial.

*Funding Opportunity Number:* SM 04-004.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 93.243.