

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 FDA identified the draft guidance document entitled "Class II Special Controls Guidance Document: Human Dura Mater; Draft Guidance for Industry and FDA" as the special control, in conjunction with general controls, that is capable of providing reasonable assurance of safety and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FDA invited interested persons to comment on the draft guidance by January 21, 2003.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.

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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.

Due Date for Applications: February 27, 2004.

You will be notified by postal mail that your application has been received.

Note: Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due April 27, 2004.

Funding Instrument: Grant.

Funding Opportunity Description: The Statewide Family Networks program is one of SAMHSA's Infrastructure Grants programs. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse service systems to support programs and services. SAMHSA's Infrastructure Grants are intended for applicants seeking Federal support to develop or enhance their service system infrastructure in order to support effective substance abuse and/or mental health service delivery. Statewide Family Network Grants are intended for applicants seeking Federal support to act as "Agents of Transformation" in developing or enhancing their service system infrastructure in order to support effective substance abuse and/or mental health service delivery which is consumer and family driven. The Statewide Family Network Program is a critical part of the SAMHSA/CMHS effort to implement the President's New Freedom Commission on Mental Health Report.

The purpose of the Statewide Family Networks program is to enhance State capacity and infrastructure to be more oriented to the needs of children and adolescents with serious emotional disturbances and their families. The program's goals are to: (1) Strengthen organizational relationships; (2) foster leadership and business management skills among families of children and adolescents with serious emotional disturbance; and (3) identify and address the technical assistance needs of children and adolescents with serious emotional disturbances and their families. To achieve this goal, the program assists family members around the country to work with policy makers and service providers to improve services for children and adolescents with serious emotional disturbances and their families. The Statewide Family Networks Program is designed to ensure that families are the catalysts for transforming the mental health and related systems in their State by strengthening coalitions among family members, and between family members and policymakers and service providers, recognizing that family members are the best and most effective change agents.

Background: The Statewide Family Network Program builds on the work of The Child, Adolescent and Services Systems Program (CASSP), which helped to establish a child and family focus in programs serving children and adolescents with serious emotional disturbances around the country. Today, nearly every State has active family organizations dedicated to promoting systems of care that are responsive to the needs of children and adolescents with serious emotional disturbances and their families. Although significant progress has been made, further support will ensure self-sufficient, empowered networks that will effectively participate in State and local mental health services planning and health care reform activities related to improving community-based services for children and adolescents with serious emotional disturbances and their families.

Estimated Funding Available/Number of Awards: It is expected that \$2.8 million will be available to fund 43 awards in FY 2004, with a limit of one award per State. Only Category 1—Small Infrastructure Grant awards, as defined in the INF-04 PA, will be made. In general, these Category 1 awards are expected to be up to \$60,000 per year in total costs (direct and indirect). Up to 22 grantees with projects that include a youth leadership component may receive an additional \$10,000 per year. Applications without a youth leadership component that include proposed budgets that exceed \$60,000 in any year will be returned without review. Applications with a youth leadership component that include proposed budgets that exceed \$70,000 in any year will be returned without review. The actual amount available for the awards may vary, depending on unanticipated program requirements and the number and quality of the applications received. This program is being announced prior to the annual appropriation for FY 2004 for SAMHSA's programs, with funding estimates based on the President's budget request for FY 2004 and/or preliminary Congressional action on SAMHSA's appropriation. Applications are invited based on the assumption that sufficient funds will be appropriated for FY 2004 to permit funding of a reasonable number of applications hereby solicited. This program is being announced in order to allow applicants sufficient time to plan and prepare applications. Solicitation of applications in advance of a final appropriation will also enable the award of appropriated grant funds in an expeditious manner. All applicants are reminded, however, that we cannot guarantee that sufficient

funds will be appropriated to permit SAMHSA to fund any applications.

Period of Support: Awards will be made for project periods of up to three years, with annual continuations depending on the availability of funds, grantee progress in meeting program goals and objectives, and timely submission of required data and reports.

Eligible Applicants: Eligible applicants are limited to domestic private, nonprofit entities, including faith-based entities, tribal family organizations, and currently funded Statewide Family Networks grantees that: (1) Are controlled and managed by family members; (2) are dedicated to the improvement of mental health services statewide; and (3) have a Board of Directors comprised of no less than 51 percent family members. SAMHSA is limiting eligibility to family-controlled organizations because the goals of this grant program are to: strengthen the capacity of families to act as agents of transformation in influencing the type and amount of services provided to them and to their children who have a serious emotional disturbance and to ensure that their mental health care is consumer and family driven. Applicants will be required to complete and sign a Certification of Eligibility and provide necessary supportive documentation. This certification will be provided in the application kit, available from the National Mental Health Information Center, and will also be posted on the SAMHSA Web page along with the NOFA.

Additional information regarding eligibility, including program requirements and formatting requirements, is provided in the INF-04 PA. Applications that do not comply with these requirements will be screened out and will not be reviewed.

Is Cost Sharing or Matching Required: No.

Exceptions to the INF-04 and Other Special Requirements: The following information describes exceptions or limitations to the INF-04 PA and provides special requirements that pertain only to the Statewide Family Network Grants:

- *Review Criteria/Project Narrative:* Applicants for Statewide Family Networks grants are required to address the following requirements in the Project Narrative of their applications, in addition to the requirements specified in the INF-04 PA:

(1) In Section B, applicants must describe how the primary focus of the proposed project will be on training capacity, network development (*i.e.*, with other consumer and family organizations), organizational and

community readiness, and policy development to support best practices.

(2) In Section B, applicants must describe the applicant's collaborations with other family and consumer networks, the State Director of Consumer Affairs (if applicable), family representatives on the State Planning Council, and other disability groups.

(3) In Section C, applicants must describe the applicant's organizational mission and how its scope of work reflects statewide focus on families who have children, youth and adolescents up to age 18 with a serious emotional, behavior or mental disorder and are currently receiving services, or up to age 25 with a serious emotional, behavior or mental disorder and are receiving transitional services from children to adult services.

(4) In Section C, applicants must describe the extent to which the applicant's Board of Directors includes family members whose children up to age 18 with a serious emotional, behavior or mental disorder and are currently receiving services, or up to age 25 with a serious emotional, behavior or mental disorder and are receiving transitional services from children to adult services.

(5) Applicants must clearly indicate in their applications whether or not a youth leadership component is included in the proposed project. Applicants that include a youth leadership component must include relevant information about the youth leadership component in *all* sections of the Project Narrative and Supporting Documentation. For example, Section A must address the need for a youth leadership component in the State where the project will be located, Section B must include a description of the proposed approach for implementing a youth leadership component, Section C must include a description of the staff, management and related experience for the youth leadership component, and Section D must include a description of evaluation and data activities for the youth leadership component. The budget for the youth leadership component provided in Section E must be separately justified and may not exceed \$10,000.

Performance Measurement: All SAMHSA grantees are required to collect performance data so that SAMHSA can meet its obligations under the Government Performance and Results Act (GPRA). In Section D of their applications, applicants for the Statewide Family Networks program must document their ability to collect and report data on the following indicators:

- An increase of families served; and
- An increase in the number of grantees that demonstrate inclusion of consumers [adolescents and young adults transitioning to adult services] and family members in planning, policy, and service delivery decisions through (a) Having policies in place; and (b) data on consumers [adolescents and young adults transitioning to adult services] and family member participation.

SAMHSA will work with grantees to finalize a standard methodology related to these indicators shortly after award. The data collection tool is yet to be developed. Grantees will be required to report performance data to SAMHSA on an annual basis.

Application and Submission Information: Complete application kits may be obtained from: the National Mental Health Information Center at 1-800-789-2649. When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit. The PHS 5161-1 application form is also available electronically via SAMHSA's World Wide Web Home Page: <http://www.samhsa.gov> (Click on "Grant Opportunities") and the INF-04 PA is available electronically at <http://www.samhsa.gov/grants/2004/standard/Infrastructure/index.asp>.

When submitting an application, be sure to type "SM 04-004, Statewide Family Networks" in Item Number 10 on the face page of the application form. Also, SAMHSA applicants are required to provide a DUNS number on the face page of the application. To obtain a DUNS Number, access the Dun and Bradstreet Web site at <http://www.dunandbradstreet.com> or call 1-866-705-5711.

Intergovernmental Review: Applicants for this funding opportunity must comply with Executive Order 12372 (E.O. 12372). E.O.12372, as implemented through Department of Health and Human Services regulation at 45 CFR Part 100, sets up a system for State and local review of applications for Federal financial assistance. Grantees must comply with the requirements of E.O. 12372. Instructions for complying with E.O. 12372 are provided in the INF-04 PA. A current listing of State Single Points of Contact (SPOCs) is included in the application kit and is available at <http://www.whitehouse.gov/omb/grants/spoc.html>.

Public Health System Impact Statement: The Public Health System Impact Statement (PHSIS) is intended to keep State and local health officials informed of proposed health services grant applications submitted by community-based, non-governmental organizations within their jurisdictions. State and local governments and Indian tribal government applicants are not subject to the Public Health System Reporting Requirements. Instructions for completing the PHSIS are provided in the INF-04 PA.

Application Review Information: SAMHSA applications are peer-reviewed. For those programs where the individual award is over \$100,000, applications must also be reviewed by the Appropriate National Advisory Council. Decisions to fund a grant are based on the strengths and weaknesses of the application as identified by the peer review committee and approved by the National Advisory Council, and the availability of funds. Unless otherwise specified, SAMHSA intends to make not more than one award per organization per funding opportunity in any given fiscal year.

Checklist for Application Formatting Requirements: SAMHSA's desire is to review all applications submitted for grant funding. However, this desire must be balanced against SAMHSA's obligation to ensure equitable treatment of applications. For this reason, SAMHSA has established certain formatting requirements for its applications. Your application must adhere to these formatting requirements. If you do not adhere to these requirements, your application will be screened out and returned to you without review. In addition to these formatting requirements, programmatic requirements (e.g., relating to eligibility) may be specified in the NOFA. Please check the entire NOFA before preparing your application.

- Use the PHS 5161-1 application.
- The 10 application components required for SAMHSA applications must be included (*i.e.*, Face Page, Abstract, Table of Contents, Budget Form, Project Narrative and Supporting Documentation, Appendices, Assurances, Certifications, Disclosure of Lobbying Activities, and Checklist.)
 - Text must be legible.
 - Paper must be white paper and 8.5" by 11.0" in size.
 - Pages must be single-spaced with one column per page.
 - Margins must be at least one inch.
 - Type size in the Project Narrative cannot exceed an average of 15 characters per inch when measured with a ruler. (Type size in charts, tables,

graphs, and footnotes will not be considered in determining compliance.)

- Photo reduction or condensation of type cannot be closer than 15 characters per inch or 6 lines per inch.

- Pages cannot have printing on both sides.

- Page limitations specified for the Project Narrative (25 pages) and Appendices 1, 3, and 4 (30 pages) cannot be exceeded.

- Information provided must be sufficient for review.

- Applications must be received by the application deadline. Applications received after this date must have a proof of mailing date from the carrier dated at least 1 week prior to the due date. Private metered postmarks are not acceptable as proof of timely mailing. Applications not received by the application deadline or postmarked a week prior to the application deadline will not be reviewed.

- Applications that do not comply with the following requirements and any additional program requirements specified in the NOFA, or are otherwise unresponsive to PA guidelines, will be screened out and returned to the applicant without review:

- Provisions relating to confidentiality, participant protection and the protection of human subjects specified in Section VIII-A of this document.

- Budgetary limitations as specified in Sections I, II and IV-E of this document.

- Documentation of nonprofit status as required in the PHS 5161-1.

To facilitate review of your application, follow these additional guidelines. Failure to follow these guidelines will not result in your application being screened out. However, following these guidelines will help reviewers to consider your application.

- Please use black ink and number pages consecutively from beginning to end so that information can be located easily during review of the application. The cover page should be page 1, the abstract page should be page 2, and the table of contents page should be page 3. Appendices should be labeled and separated from the Project Narrative and budget section, and the pages should be numbered to continue the sequence.

- Send the original application and two copies to the mailing address in the PA. Please do not use staples, paper clips, and fasteners. Nothing should be attached, stapled, folded, or pasted. Do not use any material that cannot be copied using automatic copying machines. Odd-sized and oversized attachments such as posters will not be

copied or sent to reviewers. Do not include videotapes, audiotapes, or CD-ROMs.

Award Administration: Award information, including information about award notices, administrative requirements and reporting requirements, is included in the INF-04 PA.

Contact for Additional Information: Elizabeth Sweet, SAMHSA/CMHS, Child, Adolescent and Family Branch, Center for Mental Health Services, 5600 Fishers Lane, Room 11C-16, Rockville, MD 20857; 301-443-1333; E-mail: esweet@samhsa.gov.

Dated: December 12, 2003.

Anna Marsh,

Acting Executive Officer, Substance Abuse and Mental Health Services, Administration.

[FR Doc. 03-31158 Filed 12-17-03; 8:45 am]

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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 Consumer 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 Consumer 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 Consumer Network Grants. Additional instructions and requirements specific to Statewide Consumer Network Grants are described below.

Funding Opportunity Title: Statewide Consumer Network Grants (Short Title: Statewide Consumer Networks).

Announcement Type: Initial.

Funding Opportunity Number: SM 04-003.

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

Due Date for Applications: February 25, 2004.

You will be notified by postal mail that your application has been received.

[NOTE: Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due April 25, 2004.]

Funding Instrument: Grant.

Funding Opportunity Description: The Statewide Consumer Networks program is one of SAMHSA's Infrastructure Grants programs. SAMHSA's Infrastructure Grants provide funds to increase the capacity of mental health and/or substance abuse service systems to support programs and services. SAMHSA's Infrastructure Grants are intended for applicants seeking Federal support to develop or enhance their service system infrastructure in order to support effective substance abuse and/or mental health service delivery. Statewide Consumer Network Grants are intended for applicants seeking Federal support to act as "Agents of Transformation" in developing or enhancing their service system infrastructure in order to support effective substance abuse and/or mental health service delivery which is consumer driven. The Statewide Consumer Network Grant Program is a critical part of the SAMHSA/CMHS efforts to implement the recommendations of the Final Report of the President's New Freedom Commission on Mental Health.

The purpose of the Statewide Consumer Networks program is to enhance State capacity and infrastructure to be consumer-centered and targeted toward recovery and resiliency and consumer-driven by promoting the use of consumers as agents of transformation. The program goals are to (1) strengthen organizational relationships; (2) promote skill development with an emphasis on leadership and business management; and (3) identify technical assistance needs of consumers and provide training and support to ensure that they are the catalysts for transforming the mental health and related systems in their State. To achieve this goal, the program assists consumer organizations around the country to work with policymakers and services providers to improve services for consumers with a serious mental illness. The Program is designed to strengthen coalitions among consumers, policymakers and service providers, recognizing that the