DEPARTMENT OF HEALTH SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 02N–0370]

Neurological Devices; Classification of Human Dura Mater

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify human dura mater intended to repair defects in human dura mater into class II (special controls). The agency is publishing the recommendations of FDA's Neurological Devices Panel (the Panel) regarding the classification of this device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device. This action is being taken to establish sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that FDA intends to serve as the special control for this device.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments are to be identified with the docket number found in brackets in the heading of this document.

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

A. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Admendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such

assurance. Special controls may include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency considers necessary (section 513(a)(1)(B) of the act).

Under section 513 of the act, devices that were in commercial distribution prior to May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee, regarding the classification of this device.

B. Regulatory History

Human dura mater derived and processed from human cadavers and intended for use in neurosurgical procedures to repair defects in the cranial and spinal cord dura mater caused by trauma and tumor resection was in commercial distribution before the enactment of the 1976 amendments. Human dura mater is currently regulated as an unclassified medical device via premarket notification.

In February 1987, the first of three United States cases of iatrogenic Creutzfeldt-Jacob Disease (CJD), a rare, degenerative, fatal disease of the central nervous system was reported (Ref. 1). It was associated with the implantation of Lyodura, an imported processed human dura mater manufactured in Germany that was never cleared for use in the United States. In April 1987, FDA issued a safety alert that warned of the potential risk of transmitting CJD through this imported dura mater product, and in June 1987, FDA issued an import alert banning its use in the United States.

On July 14, 1989, and on February 2, 1990, the Panel heard testimony on the processing and use of human dura mater in the United States (Refs. 2 and 3). At the 1990 meeting, in accordance with FDA's device classification regulations, the Panel recommended that human dura mater be classified into class II.

On June 26, 1990, FDA made available the ‘‘Guide for 510(k) Review of Processed Human Dura Mater.’’ The guide was based on testimony heard at the 1989 and 1990 Panel meetings. It recommended donor selection and rejection criteria, manufacturing controls, and other safeguards to minimize the risk of iatrogenic transmission of CJD. On November 14, 1990, FDA also notified distributors of human dura mater of the requirement to register and list their products with the agency and of the requirement for premarket notification clearance to market new human dura products.

On March 27, 1997, the World Health Organization (WHO) recommended that human dura mater no longer be used, especially for neurosurgery, unless no other alternative was available. WHO issued this recommendation because of over 50 cases of CJD associated with use of human dura mater (Ref. 4) . Most of these cases were associated with the dura mater product that was never cleared in the United States and that was under import alert in the United States. WHO also recommended that if human dura mater is used, it should be from nonpooled sources from carefully screened donors and it should be inactivated by a validated method.

On March 31, 1997, FDA announced that it would not restrict the distribution of FDA-cleared human dura mater because of the previously established safeguards and guidelines that were in effect to minimize the possibility of CJD transmission by human dura mater implantation. This decision also reflected the absence of any confirmed cases of CJD transmission in the United States that were related to human dura mater implants that were cleared for commercial distribution. In addition, FDA decided to hold public meetings of the agency’s Transmissible Spongiform Encephalopathies Advisory

Committee (TSEAC) to re-evaluate the safety of human dura mater with respect to CJD transmission.

On October 6, 1997, the TSEAC made recommendations on the use of human dura mater in the context of the risks to health associated both with the use of human dura mater and with the use of the available dura mater substitute products (animal, synthetic, and patient's own tissue) (Ref. 5). The TSEAC also made recommendations for additional safeguards to minimize iatrogenic CJD transmission. On March 6, 1998, FDA transmitted the 1997 TSEAC recommendations in a letter to manufacturers of human dura mater. On April 16, 1998, the TSEAC again deliberated on iatrogenic CJD transmission associated with the use of human dura mater and made additional recommendations to minimize CJD transmission.

On December 14, 1998, FDA issued a tracking order (21 CFR part 821 and section 519(e) of the act (21 U.S.C. 360i(e)) for human dura mater. This tracking order requires each manufacture of human dura mater to develop and implement a program that enables the manufacturer to locate patients implanted with human dura mater until device explantation or death.

In parallel with the Center for Devices and Radiological Health's (CDRH's) efforts to ensure the safety and effectiveness of human dura mater, FDA has considered the appropriate way to regulate all human cellular and tissue-based products (HCT/Ps). In the **Federal Register** of March 4, 1997 (62 FR 9721), FDA proposed a comprehensive approach to regulate all HCT/Ps, including human dura mater, under the authority of section 361 of the Public Health Act. To implement this approach, FDA published the following three proposed rules: (1) ''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products'' (63 FR 26744, May 14, 1998); (2)

‘‘Suitability Determination for Donors of Human Cellular and Tissue-Based Products’’ (64 FR 52696, September 30, 1999); and (3) ‘‘Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement’’ (65 FR 1508, January 8, 2001).

In the **Federal Register** of January 19, 2001 (66 FR 5447), FDA issued a final rule for establishment registration and listing of human cellular and tissue-based products (HCT/Ps). This regulation became effective on April 4, 2001, except for 21 CFR 207.20(f) (registration of drug products), 21 CFR 807.20(d) (registration of medical devices), and § 1271.3(d)(2) (21 CFR 127.3(d)(2)) (definitions), which will become effective on January 21, 2003. Section 1271.3(d)(2) also states that human dura mater is an HCT/P. In the final rule, the agency recognized that unanticipated delays in completing the rulemaking for the remainder of 21 CFR part 1271 could occur and that it could become necessary to delay the effective dates for some or all HCT/Ps.

On August 15, 2001, Public Citizen’s Health Research Group submitted a petition (docket number 01P–0354) requesting that the agency ban the sale of human cadaveric dura mater and recall all unimplanted human cadaveric dura mater. On February 11, 2002, FDA denied the petitioner’s requests in a letter because the agency determined that information in the petition did not meet the statutory requirements to ban or recall a medical device under sections 516(a)(1) and (a)(2) and 518(e)(1) of the act (21 U.S.C. 360f(a)(1) and (a)(2) and 360h(e)(1)).

FDA is now proposing to classify human dura mater into class II. The agency is also proposing that the guidance document entitled ‘‘Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA’’ be the special control to reasonably ensure the safety and effectiveness

of the device until such time as the regulatory authority for this product is transferred from CDRH to the Center for Biologics Evaluation and Research. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this draft guidance document.

II. Recommendations of the Panel

A. Device Identification

The Panel adopted the following device identification based on the agency's recommendation: Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

B. Recommended Classification of the Panel

During a public meeting on February 2, 1990, the Panel recommended that human dura mater be classified into class II (Ref. 3). The Panel also identified the following risks to health associated with the device: Prion infection, infection in general, leakage of cerebral spinal fluid (CSF), and adverse tissue reaction. New information about the safety and effectiveness of the device became available after 1990, however, and a second Panel meeting was held on September 16 and 17, 1999. At this meeting the Panel again recommended that the device be classified into class II (Ref. 6). The Panel recommended the following as potential special controls to provide reasonable assurance of safety and effectiveness: (1) FDA guidances, (2) postmarket surveillance, (3) patient registries, (4) device tracking, and (5) restrictions on donor selection.

C. Summary of the Reasons for the Recommendation

After reviewing the information provided by FDA, and after consideration of the open discussions during the Panel meeting(s) and the Panel members' personal knowledge of and clinical experience with the device system, the

Panel gave the following reasons in support of its recommendation to classify the generic type human dura mater for use in repairing defects in human dura mater into class II .

The Panel believes that human dura mater should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

D. Summary of the Data Upon Which the Recommendation is Based

In addition to the potential risks associated with the use of the human dura mater described in section V of this document, there is reasonable knowledge of the benefits of the device. Specifically, this long-term implanted device provides mechanical support and protection of the brain, as well as less leakage of CSF after neurosurgery. The use of human dura mater rather than the use of a dura substitute device or a graft prepared from the patient is also preferred by some neurosurgeons (Refs. 5 and 6).

E. Risks to Health

After considering the Panel's deliberations, as well as the published literature and medical device reports (MDRs), FDA has evaluated the risks to health associated with the use of human dura mater intended to repair defects in human dura mater. FDA now believes the following are risks to health associated with the use of the device: Infection related to patient condition and treatment, transmission of spongiform encephalopathies, leakage of CSF, and adverse tissue reaction:

1. Infection Related to Patient Condition and Treatment

Bacterial, fungal, and viral infection is a risk to health associated with all surgical procedures and implanted devices. Regarding human dura mater implantation, infection may occur because the device was improperly sterilized or because of a pre-existing patient condition (i.e., whether the wound is clean, contaminated, or infected). After the implantation of human dura mater, the probability of infection that may occur has been reported to vary from 1.9 percent to 19 percent (Refs. 7 to 9).

2. Transmission of Spongiform Encephalopathies

Transmission of CJD and related diseases can occur from either inadequate donor selection or inappropriate human dura mater processing (Refs. 10 to 12). As of July 2000, the worldwide incidence of iatrogenic CJD associated with the use of implanted human dura mater was reported to be 114 cases, including three United States cases (Ref. 13). Most of these cases were related to the use of implanted Lyodura, a product that is not cleared for use in the United States.

3. Leakage of CSF

Leakage of CSF after neurosurgery may occur due to device failure or the incomplete repair of suture holes in the patient's dura mater created during implantation of human dura mater. Leakage of CSF can cause secondary complications, such as meningitis or encephalitis, pneumocephalus, and chronic subdural hematoma. Persistent accumulation of CSF may require additional surgical intervention and can be a significant cause of morbidity and mortality (Ref. 14).

4. Adverse Tissue Reaction

Human dura mater implantation may elicit an undesirable immunological reaction (Ref. 15) and an inflammatory or cytotoxic tissue reaction (Ref. 16). These reactions may result in adverse clinical outcomes, such as adhesion formation, hydrocephalus, foreign body reactions, and seizure (Ref. 17).

F. Special Controls

Based on the available information, FDA believes that the FDA guidance document entitled ‘‘Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA’’ in addition to general controls, can provide reasonable assurance of the safety and effectiveness of the device. FDA agrees with the Panel that careful donor selection and testing guidelines are appropriate special controls to address the risks to health described in section II.E of this document. In addition, as noted below, device tracking, prescription labeling, and a form of postmarket surveillance that are already in effect provide additional controls to reasonably ensure the safety and effectiveness of human dura mater.

FDA notes that this proposed special control guidance document updates and will supersede the ‘‘Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater’’ issued on July 31, 1999, and reissued in October 1999.

1. Guidance Document

FDA believes that the guidance document addresses the Panel’s concerns on donor selection and testing guidelines.

a. *Infection related to patient condition and treatment.* Adherence to the sections in the guidance document on: (1) Donor qualification; (2) qualification of other components; (3) manufacturing processing methods; (4) manufacturing

controls; and (5) final sterilization may control the risk of bacterial, fungal, and viral infection by helping to ensure that the device is sterile and safe for long-term implantation.

b. *Transmission of spongiform encephalopathies.* Adherence to the sections in the guidance document on: (1) Donor qualification, (2) qualification of other components, (3) manufacturing processing methods, (4) manufacturing controls, and (5) labeling may control the risk of spongiform encephalopathy transmission by helping ensure the preparation of devices that have a lower risk of CJD transmission and can remind users of potential risks and alternative products.

c. *Leakage of CSF.* Adherence to the sections in the guidance document on: (1) Manufacturing processing methods, and (2) manufacturing controls can control the risk of CSF leakage by having the manufacturer demonstrate that the device is safe for long-term implantation.

d. *Adverse tissue reactions.* Adherence to the sections in the guidance document on: (1) Manufacturing processing methods, (2) manufacturing controls, and (3) final sterilization can control the risk of adverse tissue reactions by having the manufacturer demonstrate that the device is safe for long-term implantation.

2. Device Tracking

The Panel also identified device tracking as a potential special control for human dura mater. Tracking is a compliance mechanism to facilitate notification and recall actions in the event of a serious risk to health presented by a device. FDA notes that the agency has already issued a tracking order for human dura mater on December 14, 1998. Because device tracking is a regulatory control already in effect for human dura mater, it is not necessary

that tracking also be considered a special control necessary to provide reasonable assurance of the safety and effectiveness of the device.

3. Postmarket Surveillance and Patient Registries

The Panel stated that it was important to track adverse device outcomes through postmarket surveillance. FDA agrees with the Panel that adverse device outcomes should be reported to FDA. However, FDA believes that the existing mandatory MDR system is an appropriate mechanism to report such adverse events. Therefore, it is not necessary that postmarket surveillance be designated a special control.

The Panel also recommended patient registries as a special control for the device. Because the tracking regulation already requires manufacturers to develop and implement programs to locate patients implanted with human dura mater until device explantation or death, it is not necessary that patient registries be designated as a special control.

4. Prescription Labeling

The Panel also recommended that the prescription statement be a special control for the device. Prescription labeling is already required for human dura mater under 21 CFR 801.109. Therefore, it is not necessary that the prescription statement be designated a special control.

III. Proposed Classification

FDA concurs with the Panel's recommendation that human dura mater should be classified into class II. FDA believes that the special control described in section II.F of this document, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the

device, and there is sufficient information to establish special controls to provide such assurance.

The agency proposes to amend § 882.1 by adding paragraph (e) to provide availability information for guidance documents.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

FDA has also examined the impact of the proposed rule under the Regulatory Flexibility Act. The purpose of this proposed rule is to change the classification of human dura mater from an unclassified medical device into

a class II medical device subject to special controls. As an unclassified device, this device is already subject to premarket notification and the general labeling provisions of the act. There are currently five to seven manufacturers of human dura mater medical devices. All of the firms meet the Small Business Administration's definition of a small entity (fewer than 500 employees). FDA believes that manufacturers presently marketing this device generally conform to the proposed special controls guidance document. New manufacturers of human dura mater will only need to submit 510(k)s, as the statute now requires them to do, and demonstrate that they meet the recommendations of the guidance or in some way provide equivalent assurances of safety and effectiveness. In addition, biocompatibility and structural testing recommendations are eliminated from the proposed guidance, which will decrease the premarket notification costs for manufacturers introducing new human dura mater devices into commercial distribution. The agency therefore certifies that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

The premarket notification information collections addressed in the guidance document have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) under OMB control number 0910–0120. The labeling provisions addressed in the

guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

VII. Submission of Comments and Proposed Dates

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this proposal. You must submit two copies of any mailed comments except that individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may see any comments received in the Dockets Management Branch between 9 a.m and 4 p.m., Monday through Friday. FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

VIII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control, ‘‘Rapidly Progressive Dementia in a Patient Who Received a Cadaveric Dura Mater Graft,’’ *Morbidity and Mortality Weekly Report*, 36:49–50, 1987.

2. Neurological Devices Panel meeting, transcript, July 14, 1989, pp. 1–141.

3. Neurological Devices Panel meeting, transcript, February 2, 1990, pp. 5–111.

4. Centers for Disease Control, ‘‘Creutzfeldt-Jakob Disease Associated With Cadaveric Dura Mater Grafts–Japan, January 1979–May 1996,’’ *Morbidity and Mortality Weekly Report*, 46: 1066–1069, 1997.

5. Transmissible Spongiform Encephalopathies Advisory Committee meeting, transcript, October 6 and 7, 1997, pp. 210–269.

6. Neurological Devices Panel meeting, transcript, September 16, 1999, pp. 1–3 and 77–99, and September 17, 1999, pp. 9–11 and 17–101.

7. Abbott, W. M. and E. L. Dupree, ‘‘Clinical Results of Lyophilized Human Cadaver Dura Transplantation,’’ *Journal of Neurosurgery*, 34: 770–773, 1971.

8. Cantore, G., G. B. Guidetti, and R. Delfini, ‘‘Neurosurgical Use of Human Dura Mater Sterilized by Gamma Rays and Stored in Alcohol: Long-Term Results,’’ *Journal of Neurosurgery*, 66: 93–95, 1987.

9. Laun, A., J. C. Tonn, and C. Jerusalem, ‘‘Comparative Study of Lyophilized Human Dura Mater and Lyophilized Bovine Pericardium as Dural Substitutes in Neurosurgery,’’ *Acta Neurochirurgica* (Wien), 107: 1621, 1990.

10. Thadani, V., P. L. Penar, J. Partington, R. Kalb, R. Janssen, L. B. Schonberger, C. S. Rabkin, and J. W. Prichard, ‘‘Creutzfeldt-Jakob Disease Probably Acquired From a Cadaveric Dura Mater Graft, Case Report,’’ *Journal of Neurosurgery*, 69: 766–769, 1988.

11. Lang, C. J., J. G. Heckman, and B. Neundorfer, ‘‘Creutzfeldt-Jakob Disease Via Dural and Corneal Transplants,’’ *Journal of Neurological Science*, 160: 128–139, 1998.

12. Dobbins, J. G., E. D. Belay, J. Malecki, B. E. Buck, M. Bell, J. Cobb, and L. B. Schonberger, ‘‘Creutzfeldt-Jakob Disease in a Recipient of a Dura Mater Graft Processed in the U.S.: Cause or Coincidence?’’ *Neuroepidemiology*, 19: 62–66, 2000.

13. Brown, P., M. Preece, J. P. Brandel, T. Sato, L. McShane, I. Zerr, A. Fletcher, R. G. Will, M. Pocchiari, N. R. Cashman, J. H. d’Aignaux, L. Cervenakova, J. Fradkin, L. B. Schonberger, and S. J. Collins, ‘‘Iatrogenic Creutzfeldt-Jacob Disease at the Millenium,’’ *Neurology*, 55: 1075–1081, 2000.

14. Sawamura, Y., K. Asaoka, S. Terasaka, M. Tada, and T. Uchida, ‘‘Evaluation of Application Techniques of Fibrin Sealant to Prevent Cerebrospinal Fluid Leakage: A New Device for the Application of Aerosolized Fibrin Glue,’’ *Neurosurgery*, 44: 332–337, 1999.

15. Alleyne, C. H. and D. L. Barrow, ‘‘Immune Response in Hosts With Cadaveric Dural Grafts,’’ *Journal of Neurosurgery*, 81: 610–613, 1994.

16. Rosomoff, H. L. and T. I. Malinin, ‘‘Freeze-Dried Allografts of Dura Mater—20 Years Experience,’’ *Transplantation Proceedings*, VIII: No. 2 Supplement 1, 133–138, 1976.

17. Sharkey, P. C., F. C. Usher, R. C. L. Robertson, and C. Pollard, ‘‘Lyophilized Human Dura Mater as a Dural Substitute, ’’ *Journal of Neurosurgery*, 15: 192–198, 1958.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c 360e, 360j, 371.

2. Section 882.1 is amended by adding paragraph (e) to read as follows:

§ 882.1 Scope.

* * * * *

(e) Guidance documents in this part may be obtained on the Internet at http://www.fda.gov/cdrh/guidance.html.

3. Section 882.5975 is added to subpart F to read as follows:

§ 882.5975 Human dura mater.

(a) *Identification*. Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) *Classification*. Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA.'' (See § 882.1 for availability information for guidances.)

Dated: September 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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