unpublished data was conducted to substantiate that the safety can be assured if cranial orthoses are exempted from the requirements of premarket notification. Some of the public comments identified literature regarding additional safety issues that had not been identified by the petitioner.

One comment generally supported the petition, but stated that cranial orthoses indicated for posterior plagiocephaly should either have fabrication restrictions removed or the device should be pulled from the market until efficacy data is provided. FDA disagrees with this comment. Cranial orthoses are class II devices with special controls, including the requirement for premarket notification. This has assured reasonable safety and effectiveness for use with infants having posterior plagiocephaly.

Eleven comments stated that current regulation requirements inflate cost. Additionally, four comments stated that current regulation requirements decrease accessibility. FDA has no comment because neither issue is a criterion for exemption of a class II device.

B. Comments Opposing the Petition for Exemption

FDA received 26 comments (29 individuals; 3 letters had 2 signatures) opposing an exemption from premarket notification for these devices, including:

Twenty-four comments stated that exemption would fail to provide reasonable assurance of the safety and effectiveness of these devices. One comment states that special controls are required to ensure reasonable safety and effectiveness.

FDA agrees that insufficient information is available in the petition for FDA to make a determination that premarket clearance is not necessary to provide reasonable assurance of safety and effectiveness. FDA also agrees that special controls are required in order to address the health risks associated with inherent characteristics and indications of this class II device, and FDA has established special controls for the device (63 FR 40650). In addition, we have previously determined that premarket notification review and clearance was necessary prior to introducing the device into commercial distribution. As discussed previously, the petitioner did not provide sufficient information, which might include special controls, to address the health risks associated with cranial orthoses and that would sufficiently address the factors FDA considers important in determining whether to grant an exemption of a class II device.

One comment stated that there are no documented industry fabrication standards.

FDA believes this comment refers to the lack of recognized voluntary standards. FDA agrees and notes that it has not recognized any consensus standards relevant to the fabrication of cranial orthoses that would suffice as special controls, which could sufficiently address the factors FDA considers important in determining whether to grant an exemption of a class II device.

Nineteen comments stated that cranial orthoses should be regulated because they are indicated for a vulnerable population. One comment stated that the complexity of medical conditions that result in the need for treatment with these devices is just starting to be reported in the medical literature.

FDA believes that the level of regulation needed for this condition in a vulnerable population is commensurate with class II, including special controls. The petition provided insufficient information for developing special controls that would provide reasonable assurance of safety and effectiveness, when used on infants with complex medical conditions, if this type of device was exempt from premarket notification.

Four comments stated the petition has insufficient information for addressing the factors FDA considers important in determining whether to grant an exemption of a class II device from premarket notification, FDA agrees, as discussed earlier.

One comment stated that exemption of cranial orthoses will allow unqualified individuals to treat these patients and lower the standard of care. FDA does not regulate the qualifications of healthcare practitioners. However, regardless of whether a class II device is exempt from premarket notification, FDA can require prescription use labeling for class II devices. Prescription use labeling is required for this type of device.

Five comments stated that access has not been deterred by the Class II designation. Three comments stated that there is insufficient evidence that innovation has been deterred by the Class II designation. Five comments stated that price increases are due to the significant increase in the service-intensity of this therapy. FDA has no comment because none of these issues is a criterion for exemption of a class II device.

V. Order

After reviewing the petition and for the reasons explained previously, FDA has determined that the petition failed to provide information that premarket clearance is not necessary to provide reasonable assurance of safety and effectiveness. Therefore, FDA is issuing this order denying the petition requesting exemption for cranial orthosis from the premarket notification requirements.

Dated: December 19, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–22072 Filed 12–22–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. This meeting was originally announced in the **Federal Register** of December 6, 2006 (71 FR page 70780). The amendment is being made to reflect a change in the *Agenda* portion of the document, specifically to include the name of the sponsors and devices. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3737, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 6, 2006, FDA announced that a meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee would be held on January 26, 2007. On page 70780, column 1, the *Agenda* portion of the document is amended to read as follows:

Agenda: The committee will discuss and make recommendations on a premarket notification application, sponsored by Neuronetics, Inc., for the NeuroStar System for the treatment of major depressive disorder. The

committee will also hear and discuss post approval study reports for two recently approved neurological device premarket approval applications: The VNS Therapy™ System, sponsored by Cyberonics, Inc., for treatment-resistant chronic or recurrent depression; and the Dural Sealant System, sponsored by Confluent Surgical, Inc., for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

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

Dated: December 18, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–21995 Filed 12–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227. 414–328–7840/800–877–7016. (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624. 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118. 901–794–5770/888–290–1150.

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210. 615–255–2400.

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299. 501–202–2783. (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802. 800–445–6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913. 239–561–8200/800–735–5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602. 229–671–2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974. 215–674–9310.

Dynacare Kasper Medical Laboratories,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2. 780–451–3702/800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655. 662–236–2609.

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4. 519–679–1630.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715. 608–267–6225.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053. 504–361–8989/800–433–3823. (Formerly: Laboratory Specialists, Inc.).

Kroll Scientific Testing Laboratories, Inc., 450 Southlake Blvd., Richmond, VA 23236. 804–378–9130. (Formerly: Scientific Testing Laboratories, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040. 713–856–8288/800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869. 908–526–2400/800–437–4986. (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709. 919–572–6900/800–833–3984. (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 10788 Roselle St., San