AUTHORITY FOR MAINTAINING THE SYSTEM: PUB. L. 92–255 AND 5 U.S.C. 7904.

PURPOSE:

To maintain an information system on employees suspected of abusing or known to abuse alcohol or another drug and for self-initiated referrals.

ROUTINE USES OF THE RECORD SYSTEM, INCLUDING TYPES OF USERS AND THEIR PURPOSES IN USING IT:

Disclosing information related to anyone with a history of alcohol or drug abuse is restricted by Alcohol and Drug Abuse Patient Records regulations, 42 CFR part 2.

System information may be accessed and used by authorized Federal agency employees or contractors to conduct official duties. Information from this system also may be disclosed as a routine use:

a. Documenting that the supervisor deals properly with an employee whose work is affected by alcohol abuse or other drug abuse.

b. Communicating information to those who use it in performing their duties, such as a counselor, medical or health worker, an alcohol or other drug abuse program administrator, or a qualified service organization.

c. Disclosing information to the Department of Justice or another Federal agency in defending a claim against the United States, when the claim is based on a person's mental or physical condition and is allegedly caused by GSA activities affecting the person.

d. In any legal proceeding, where pertinent, to which GSA is a party before a court or administrative body.

e. To authorized officials engaged in investigating or settling a grievance, complaint, or appeal filed by an individual who is the subject of the record.

f. To a Federal agency in connection with the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation; the letting of a contract; or the issuance of a grant, license, or other benefit to the extent that the information is relevant and necessary to a decision.

g. To the Office of Personnel Management (OPM), the Office of Management and Budget (OMB), or the Government Accountability Office (GAO) when the information is required for program evaluation purposes.

h. To a Member of Congress or staff on behalf of and at the request of the individual who is the subject of the record.

i. To an expert, consultant, or contractor of GSA in the performance of a Federal duty to which the information is relevant.

j. To the National Archives and Records Administration (NARA) for records management purposes.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are kept in a file cabinet or in a drawer.

RETRIEVABILITY:

The records are filed alphabetically by name.

SAFEGUARDS:

When not in use by an authorized person, the records are stored in a locked metal file cabinet or in a secured room.

RETENTION AND DISPOSAL:

The records are kept for a year after the employee's last contact with a counselor or until the employee separates or transfers, whichever occurs first. If there is an EEO case, MSPB appeal, or arbitration, the records are kept for 3 years after the case is resolved. Records are destroyed by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

The Director, Human Capital Policy and Program Management Division (CHP), Office of Human Capital Management (CH), 1800 F Street NW, Washington, DC 20405.

NOTIFICATION PROCEDURE:

An employee may obtain information as to whether he or she is part of the system of records from the immediate supervisor or the Director of Human Capital Policy and Program Management Division at the address above, whichever is appropriate.

RECORD ACCESS PROCEDURE:

A request to review a record related to you should be directed to the immediate supervisor or Director of Human Capital Policy and Program Management Division at the address above, whichever is appropriate. For the identification required, see 41 CFR part 105–64 published in the **Federal Register**. Procedure to contest a record: GSA rules to review the content of a record and appeal an initial decision are in 41 CFR part 105–64 published in the **Federal Register**.

RECORD SOURCES:

The supervisor(s), counselors, personnel specialists, and individual employee.

[FR Doc. E6–22003 Filed 12–22–06; 8:45 am]

BILLING CODE 6820–34–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0085]

Medical Devices; Exemptions from Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order denying a petition requesting exemption for cranial orthosis type devices from the premarket notification requirements for certain class II devices. A cranial orthosis device is a device intended to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry or shape. FDA is publishing this notice in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This order is effective December 26, 2006.

FOR FURTHER INFORMATION CONTACT: Heather Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4040.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-

supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes.

Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added section 510(m) to the act. Section 510(m)(l) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(l), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

FDA classified the cranial orthosis into class II (special controls) effective August 31, 1998 (63 FR 40650, July 30, 1998). The classification regulation for cranial orthosis is at 21 CFR 882.5970. The cranial orthosis is identified as a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

II. Criteria for Exemption

There are a number of factors FDA may consider when determining whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device, including the factors discussed in the guidance entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (available at *http://www.fda.gov/cdrh/modact/exemii.pdf* or by sending a fax request to 240–276–3151 to receive a hard copy). The factors outlined in the guidance included: (1) The device does not have a significant history of false or misleading claims or risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive or negative controls, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA also considered that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Petition

FDA received a petition requesting an exemption from premarket notification for class II devices, 21 CFR 882.5970 Cranial orthosis, from Catherine Jeakle Hill, on behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Section on Pediatrics.

On October 24, 2006 (71 FR 62268), FDA published a notice announcing that this petition had been received and providing an opportunity for interested persons to submit comments on the petition by November 24, 2006.

IV. Summary of Public Comments

FDA received a total of 39 comments (42 individuals; 3 letters had 2 signatures) regarding this petition. We have summarized the comments as follows:

A. Comments Supporting the Petition for Exemption

FDA received 13 comments supporting an exemption from premarket notification for this type of device, including:

Four comments stated that cranial orthoses have similar risks and technological considerations as those used for Class I exempt orthotics for use on other parts of the body.

FDA disagrees. FDA has identified specific health risks inherent to the cranial orthosis indications and technological characteristics (63 FR 40650). Some of the literature referenced by the petitioner also identified the risks inherent to cranial orthoses, e.g., restriction of cranial growth.

Eleven comments supported the petition stating that cranial orthoses are safe, and four comments stated that long term use is evidence of efficacy. One comment stated that the limitations to the exemption are sufficient for monitoring changes in intended use and technology. However, FDA believes that the petition failed to provide information, including potential special controls, to establish that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness and to assure that health risks associated with inherent characteristics of the device and indications are addressed. Additionally, the petition failed to describe how changes in the device that could lead to device failures would either: (1) Be readily detectable by users by visual examination or other means, such as routine testing, before causing harm; or (2) not materially increase the risk of injury or ineffective treatment.

In addition, the petitioner did not provide sufficient information to address the frequency, persistence, cause, or seriousness of the inherent risks of the device or to establish special controls to address the health risks associated with cranial orthoses. The petitioner did not specify whether a comprehensive search of the medical literature and other available,

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]

BILLING CODE 4160–01–S

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