provides statistical support including the collection, processing, compilation, computation, analysis, editing, and/or presentation of statistical data to CDC; and provides, upon request and on a self-initiated basis, technical assistance, demonstrations, and consultation on technical matters pertaining to occupational safety and health to other Federal agencies, state, and local agencies, other agencies, other technical groups, unions, employers, and employees.

Statistical Support Most Efficient Organization (CCKE). (1) Provides statistical support including the collection, processing, compilation, computation, analysis, editing and/or presentation of statistical data; (2) provides technical statistical support to professionals as they analyze and prepare reports on statistical studies and surveys; (3) provides information, reference, and research services; and (4) provided administrative services related to statistical support.

Delete item (5) of the functional statement of the *Community Health and Program Services Branch (CUCEG), Division of Adult and Community Health (CUCE), National Center for Chronic Disease Prevention and Health Promotion (CUC), Coordinating Center for Health Promotion (CU)*, and insert the following: (5) provides professional statistical and programming services to the division, including assistance in design of data collection instruments, computer programming, and statistical analysis.

Delete item (1) of the functional statement for the *Information Technology, Statistics, and Surveillance Branch (CUCJD), Division of Reproductive Health (CUCJ),* and insert the following: (1) Provides professional statistical and computer services to the division including statistical consultation, systems analysis, technical assistance, and resource identification.

Delete item (6) of the functional statement for the *Statistics and Data Management Branch (CVBCG), Division of Sexually Transmitted Disease Prevention (CVBC), National Center for HIV, STD, and TB Prevention (CVB), Coordinating Center for Infectious Diseases (CV),* and insert the following: (6) provides data management and professional statistical services for STD surveillance and epidemiologic studies.

Delete item (3) of the functional statement for the *Statistics and Data Management Branch (CVBED), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (CVBE),* and insert the following: (3) provides data management and statistical services for HIV/AIDS surveillance, HIV serosurveys, epidemiologic studies and other studies conducted within the division and DHAP/IRS.

Dated: October 4, 2006.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 06–8839 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0333]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Emergency Use Authorization of Medical Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 18, 2006 (71 FR 40722), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0595. The approval expires on October 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17718 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0021]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Request for Samples and Protocols'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 29, 2006 (71 FR 37080), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0206. The approval expires on September 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17720 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–01–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 announcing

that it has received a petition requesting exemption from the premarket notification requirements for cranial orthosis type devices. These devices are used to improve cranial symmetry in neonates. FDA is publishing this notice in order to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments by November 24, 2006.

ADDRESSES: Submit written comments 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory 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 a new section 510(m) to the act. Section 510(m)(1) 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)(1), 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.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web at *http://www.fda.gov/cdrh/modact/exemii.pdf* or by sending a fax request to 240–276–3151 to receive a hard copy. Specify ''159'' when prompted for the document shelf number.

III. Proposed Class II Device Exemptions

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

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before November 24, 2006. Submit a single copy of electronic comments or submit two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 13, 2006.

Linda S. Kahan,

Deputy Director, Center for Device and Radiological Health.

[FR Doc. E6–17729 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0400]

Global Harmonization Task Force, Study Groups 1, 2, 4, and 5; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the