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

availability of several proposed and final documents that have been prepared by Study Groups 1, 2, 4, and 5 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments on any of the proposed documents by January 22, 2007. After January 22, 2007, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of the guidance documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning the guidances 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:

For Study Group 1: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, ext.143.

For Study Group 2: Mary Brady, GHTF, Study Group 2, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr.,Rockville, MD 20850, 301–594–2102.

For Study Group 4: Jacqueline Welch, GHTF, Study Group 4, Office of Compliance, Center for Devices and Radiological Health (HFZ–320), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

For Study Group 5: Herbert Lerner, GHTF, Study Group 5, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 207.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by four of the Study Groups (1, 2, 4, and 5).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of its efforts, this group has developed final documents SG1/N15:2006 and SG1/N40:2006.

SG1/N15:2006 (final document) entitled ''Principles of Medical Devices Classification'' assists a manufacturer to assign its medical device to an appropriate risk class using a set of harmonized principles. This document applies to products that have a medical purpose, as described in GHTF document SG1/N29R16:2005 entitled ''Information Document Concerning the Definition of the Term 'Medical Device,''' except for those devices used for the in vitro examination of specimens derived from the human body.

SG1/N40:2006 (final document) entitled ''Principles of Conformity Assessment for Medical Devices'' describes the evidence and procedures that may be used by a manufacturer to demonstrate that a medical device is safe and performs as intended by the manufacturer, and the process by which a Regulatory Authority, or Conformity Assessment Body, may confirm that the procedures are properly applied by the manufacturer. This document applies to all products that fall within the definition of a medical device, as described in GHTF document SG1/N29R16:2005 entitled ''Information Document Concerning the Definition of the Term 'Medical Device,''' except for those devices used for the in vitro examination of specimens derived from the human body.

Study Group 2 was initially tasked with the responsibility of developing guidance documents that will be used for the exchange of adverse event reports. As a result of its efforts, this group has developed proposed document SG2(PD)/N87R7:2006, and final documents SG2/N57R8:2006 and SG2/N79R8:2006.

SG2(PD)/N87R7:2006 (proposed document) entitled ''An XML Schema for the Electronic Transfer of Adverse Event Data Between Manufacturers, Authorized Representatives and National Competent Authorities (Based on GHTF SG2 N32v5.2)'' provides details of an electronic format for manufacturers and National Competent Authorities (NCA) to use when exchanging adverse incident data electronically.

SG2/N57R8:2006 (final document) entitled ''Medical Devices: Post Market Surveillance: Content of Field Safety Notices'' identifies elements that should be included in safety related notifications issued by the medical device manufacturer. SG2/N79R8:2006 (final document) entitled ''Medical

Devices Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form'' provides guidance, procedures, and forms for the exchange of reports concerning the safety of medical devices between NCA and other participants of the GHTF National Competent Authority Report (NCAR) exchange program.

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4/N30R20:2006. SG4/N30R20:2006 (final document) entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy,'' which is intended to assist medical device regulators and organizations conducting quality management system audits to apply a process system approach to quality management system requirements (e.g. ISO 13485:2003 and 21 CFR part 820).

Study Group 5 was initially tasked with the responsibility of developing guidance documents on the content and documentation of clinical investigations. As a result of its efforts, this group has developed documents SG5(PD)N1R7:2006 and SG5(PD)N2R7.

SG5(PD)N1R7:2006 (proposed document) entitled ''Clinical Evidence—Key Definitions and Concepts'' introduces the concepts of clinical evaluation and clinical evidence, and examines the relationship between clinical investigation, clinical data, clinical evaluation, and clinical evidence. SG5(PD)N2R7:2006 (proposed document) entitled ''Clinical Evaluation'' provides guidance on how to conduct the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing a medical device on the market, as well as to support its ongoing marketing.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the guidances may also do so by using the Internet. The Center for Devices and Radiological Health (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. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17727 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–0353]

Draft Guidance for Industry and Food and Drug Administration Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Draft Guidance for Industry and FDA Staff: Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems.'' This draft guidance provides FDA's recommendations concerning portable invasive blood glucose monitoring systems (BGMSs).

DATES: Submit written or electronic comments on this draft guidance by January 22, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and FDA Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems '' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850, 240–276–0490 x117.

SUPPLEMENTARY INFORMATION:

I. Background

Portable invasive BGMS devices were introduced in the late 1970s and are considered one of the most important medical advances in diabetes care. This draft guidance document provides the FDA's recommendations concerning BGMS devices. In addition to recommendations for preparation of premarket notifications (510(k)), the draft guidance document discusses features of device design and risk management, including those relating to human factors. The draft guidance document, when finalized, is intended to complement International Standards Organization standards on risk management for medical devices and BGMSs. The scope of this draft guidance document includes BGMS devices, used in the quantitative measurement of glucose in blood by lay users at home or by professionals in hospitals and other point of care settings, to manage carbohydrate metabolism disorders including diabetes mellitus. When this guidance document is finalized, FDA expects that this guidance document will enable FDA to make more efficient and better-informed decisions based on more consistent data, and better contribute to the marketing of more