

in accordance with section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) and 21 CFR 3.4. This will consolidate primary responsibility for regulating wound care products containing live cells in CBER.

II. Web page Listing CDRH Applications Transferred to CBER and Contact Information

FDA has created a Web page listing the premarket approval applications and humanitarian device exemptions in CDRH that are being transferred to CBER. Sponsors of these products are encouraged to consult the Web page to find new contact information. The Web page address is: <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm356173.htm>.

Commencing immediately, submitters should send submissions to: Document Control Center, HFM-99, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Contact for questions on submissions: Patrick Riggins, Office of Cellular, Tissue and Gene Therapy, Center for Biologics Evaluation and Research, WOC1, Rm. 234N (HFM-705), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5366, patrick.riggins@fda/hhs.gov.

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-19685 Filed 8-13-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-D-0300] (formerly Docket No. 2006D-0504)

Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff." This guidance document is intended to assist industry and FDA staff in identifying and appropriately addressing specific considerations related to the

incorporation and integration of radio frequency (RF) wireless technology in medical devices. This guidance discusses issues that may affect the safe and effective use of medical devices that incorporate RF wireless technology, including selection of wireless technology, quality of service, coexistence, security, and electromagnetic compatibility, and provides recommendations for information to be included in FDA premarket submissions for such devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist those offices in processing your request, or fax your request to CDRH at 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donald Witters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1130, Silver Spring, MD 20993-0002, 301-796-2483; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance document to assist industry, systems

and service providers, consultants, FDA staff, and others involved in the design, development, and evaluation of RF wireless technology in medical devices. The use and deployment of RF wireless technology in and around medical devices is an increasing concern because the electromagnetic environments where medical devices are used might contain many sources of RF energy, and the RF wireless emissions from one product or device could potentially affect the function of another. The guidance recommends that manufacturers address the potential issues that relate to the incorporation of RF wireless technology that may affect the safe and effective use of medical devices.

The draft guidance document and comment period were announced in the **Federal Register** on January 3, 2007 (72 FR 137). The comment period closed on April 2, 2007. Over 25 companies, numerous organizations, and many individuals provided around 180 comments. FDA considered all of the comments and revised the guidance where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on radio frequency wireless technology in medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. To receive "Radio Frequency Wireless Technology in Medical Devices; Guidance for Industry and Food and Drug Administration Staff," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1618 to

identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (See **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19686 Filed 8–13–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the American College of Gastroenterology, the American Gastroenterological

Association, the Crohn's and Colitis Foundation of America, Inc., the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, and the Pediatric IBD Foundation, is announcing a 2-day public workshop entitled "Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT II)." Partners and stakeholders planning the workshop also include patients and representatives from the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. The purpose of this workshop is to provide a forum to consider issues related to endpoints that can support drug development in the following disease areas: Pediatric and adult inflammatory bowel diseases.

DATES: The public workshop will be held on October 21 and 22, 2013, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the National Institutes of Health, 31 Center Dr., Natcher Conference Center, Building 45, Bethesda, MD 20892–2178.

FOR FURTHER INFORMATION CONTACT: Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2302, FAX: 301–796–9905, email: Kevin.Bugin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: This workshop will address endpoints for registration trials. Stakeholders, including industry sponsors, academia, patients, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in registration trials for products intended to treat adult and/or pediatric inflammatory bowel disease. The definition and measurement of treatment benefit in Crohn's disease registration trials, the role of existing and future clinical outcome assessments including development of patient reported outcome measures, timing of endpoint assessments, and dose-finding strategies will be discussed. In addition, there will be a followup to previous workshop discussions of endpoints and clinical trial design for ulcerative colitis registration trials. Strategies and methods to overcome the challenges of developing drugs in pediatric populations and facilitate the collection of dosing, safety, and efficacy information for drugs not currently approved for use in children will be discussed.

Participation in the Public Workshop: Registration: There is no fee to attend the public workshop, but attendees

must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at <http://www.great2.org> before October 1, 2013. For those without Internet access, please contact Kevin Bugin (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kevin Bugin (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at <http://www.regulations.gov> approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.