

comment on the proposed collection of information. FDA received five comments; some comments raised more than one issue. Comments relevant to the information request are addressed in this document.

(Comment 1) One comment indicated that the intent of the notice was unclear and suggested that FDA revise and republish the notice to provide clarity and allow stakeholders more opportunity to comment.

(Response) FDA published the 60-day information collection notice (78 FR 21379) to provide an opportunity for comment on its proposed extension of an existing collection of information. The collection includes health tobacco documents created during the period June 23, 2009, through December 31, 2009, that have not been submitted to FDA. FDA does not believe that revision of the April 2013 notice would add clarity or provide a more meaningful opportunity to comment. FDA has met the requirements for the proposed extension of this collection of information.

(Comment 2) Another comment stated that FDA is outside its statutory authority in recommending coding/classification and places an unnecessary and unreasonable burden on the industry with no benefit to FDA in collecting this information.

(Response) Section 904(a)(4) of the FD&C Act grants FDA the authority to

collect health document information as specified in this document. The classification and coding mentioned in this document are recommendations from the April 2010 guidance, and FDA will reevaluate and revisit this issue in developing future guidance.

(Comment 3) Two comments indicated that the timing and burden for this collection are underestimated.

(Response) The estimated burden of 50 hours per response is based on the average burden estimate among four respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA notes that the number of documents received since the original collection period has decreased each year and is currently less than 5 percent of the number received in the year following the Agency's original announcement. FDA expects that this collection of information will decrease by 7,600 hours because most documents created within the specified period have been submitted, and the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be, at most, 5 percent of the original burden.

(Comment 4) One comment indicated that the information requested in this collection is from too narrow a collection window, and another

comment stated that the collection of 2009 information in 2013 is not necessary.

(Response) Section 904(a)(4) of the FD&C Act sets out an ongoing requirement for the submission of tobacco health documents. FDA is in the process of revising the April 2010 guidance to specify the timing of subsequent submissions. However, the Agency will continue collecting documents created during the period from June 23, 2009, through December 31, 2009, from any manufacturers, importers, or their agents who still have documents to submit.

(Comment 5) Several comments referred to the 2009 draft guidance (74 FR 68629, December 28, 2009) and to previously submitted comments on the 2009 draft guidance.

(Response) The 2009 draft guidance was superseded by publication of the April 2010 guidance. FDA considered comments on the 2009 draft guidance while developing the April 2010 guidance. Comments on Agency guidance are welcome at any time (21 CFR 10.115(g)(5)), and comments submitted on the April 2010 guidance will be considered when the guidance is revised.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| Activity                                                    | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Tobacco Health Document Submissions and Form FDA 3743 ..... | 4                     | 2                                  | 8                      | 50                          | 400         |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 8, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0842]

### Consolidation of Wound Care Products Containing Live Cells

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER). This consolidation initiative provides the opportunity to further develop and coordinate scientific and regulatory activities between CDRH and CBER. FDA believes that as more wound care products containing live cells are developed such consolidation is necessary for both efficient and consistent Agency action.

**FOR FURTHER INFORMATION CONTACT:** John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993, 301-796-8930, [john.weiner@fda.hhs.gov](mailto:john.weiner@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Consolidation of Approved Wound Care Products Containing Live Cells in CBER

On August 14, 2013, primary responsibility for regulating the following approved products: P950032, P960007, P000036, P010016, (all with product code MGR); H990013 (product code PBD); and H990002 (product code OCE), and all supplements included therein, was transferred from the Office of Device Evaluation, CDRH, to the Office of Cellular, Tissue and Gene Therapies, CBER. The jurisdictional assignment of these products to CBER is

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](mailto:patrick.riggins@fda/hhs.gov).

Dated: August 8, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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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](mailto: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