ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP	57	1	44	2,508

Estimated Total Annual Burden Hours: 2,508.

Dated: August 15, 2012.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2012–20418 Filed 8–17–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0841]

ASTM International-Food and Drug Administration Workshop on Absorbable Medical Devices: Lessons Learned From Correlations of Bench Testing and Clinical Performance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''ASTM International-FDA Workshop on Absorbable Medical Devices: Lessons Learned From Correlations of Bench Testing and Clinical Performance.'' FDA is co-sponsoring the workshop together with ASTM International, an organization responsible for the development and delivery of international voluntary consensus standards for engineered products, including medical devices. The purpose of this public workshop is to provide a forum for highlighting and discussing the use of absorbable materials in medical devices across a broad range of indications with the aim of defining successful and unsuccessful methods to predict clinical performance. The main topics to be discussed include identification of test methods for establishing correlations between in vitro and in vivo degradation of absorbable implant devices, and the interaction of mechanical loading and mechanical performance with degradation. While there will be an emphasis on cardiovascular indications as part of a panel session, characterization techniques and experiences from both cardiovascular as well as non-cardiovascular devices will be discussed and are encouraged.

Date and Time: The public workshop will be held on November 28, 2012, from 8:30 a.m. to 5 p.m. EST.

Location: The public workshop will be held at the FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD, 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Maureen Dreher, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, Bldg. 62, rm. 2110, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2505, Fax: 301–796–9932, email: *Maureen.dreher@fda.hhs.gov;* or Erica Takai, CDRH, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6353, Fax: 301–796–9959, email: *erica.takai@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by November 13, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Cindy Garris, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD, 20993–0002, 301–796–5861, email: *cynthia.garris@fda.hhs.gov,* at least 7 days in advance of the workshop.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Maureen Dreher or Erica Takai to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by November 13, 2012, 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 23, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This public workshop includes presentations in topic-focused sessions. If you wish to present at the workshop, please submit an abstract at: *http://www.astm.org/f04wkshp1112.htm.*

FDA has included general topics in this document. Following the close of the call for abstracts, FDA and ASTM International members of the workshop organizing committee will determine the amount of time allotted to each presenter, the approximate time each oral presentation is to begin, and will select and notify participants by October 1, 2012. All requests to make oral presentations must be received by the close of the call for abstracts on September 1, 2012. If selected for presentation, any presentation materials must be emailed to Maureen Dreher (see *Contact Person*) no later than November

23, 2012. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop through co-sponsorship with ASTM International to obtain information on test methods for establishing correlations between in vitro and in vivo degradation of absorbable devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is December 28, 2012.

Regardless of attendance at the public workshop, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Please 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Recent studies have identified promising results for the use of absorbable materials in implantable devices for endovascular therapies such as fully absorbable cardiovascular stents where the stent platform degrades, in addition to absorbable coatings. The use of these materials for cardiovascular indications, however, poses new risks due to the critical fatigue and mechanical loading demands that the implant must withstand and perform. Moreover, the optimal preclinical/bench testing paradigm to predict clinical performance of fully absorbable cardiovascular devices is not yet defined.

This public workshop will discuss the use of absorbable materials (including synthetic polymers as well as erodible metals) in medical devices across a broad range of indications with the aim of defining successful and unsuccessful methods to predict clinical performance, and will subsequently apply lessons learned to unique challenges for cardiovascular indications. Therefore, we invite presenters to share their experience with respect to cardiovascular and non-cardiovascular medical devices, both those that are fully absorbable and those with only a component or coating that is absorbable.

This public workshop will bring together the expertise of academia and industry professionals to define test methods as well as to educate and inform industry, academia, and device regulators on the performance and predictability of absorbable medical device degradation. Workshop participants will seek to define the critical factors for preclinical/bench testing and clinical predictability. They will then apply lessons learned from marketed devices for non-cardiovascular indications to the emerging uses of absorbable devices to treat cardiovascular disease.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Correlations of in vitro and in vivo absorption
- Quantitative characterization of absorption kinetics
- Test methods to identify interactions of absorption with mechanical loading
- Test methods to assess mechanical performance of the absorbable product

The lessons learned from both early cardiovascular and well-established non-cardiovascular device experiences will be presented. These lessons will be discussed in the context of emerging cardiovascular uses of absorbable materials as part of a panel session at the end of the workshop.

Dated: August 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20322 Filed 8–17–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 029

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 029'' (Recognition List Number: 029), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 029'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by email: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. See section