TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2012, THROUGH SEPTEMBER 30, 2012—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P080030, FDA–2012–M–0712.	Glaukos Corp	Glaukos iStent® Trabecular Micro-Bypass Stent and Inserter.	June 25, 2012.
P110007, FDA–2012–M–0734.	Abbott Medical Optics, Inc	Healon® EndoCoat OpViscosurgical Ophthalmic Device (OVD) (3% Sodium Hyaluronate).	July 2, 2012.
P110037, FDA–2012–M–0713.	Roche Molecular Systems, Inc.	COBAS® AmpliPrep/COBAS® TaqMan® CMV Test	July 5, 2012.
P110030, FDA–2012–M–0735.	QIAGEN Manchester, Ltd	*therascreen*® KRAS RGQ PCR Kit	July 6, 2012.
P110043, FDA–2012–M–0833.	Abbott Vascular	Omnilink Elite Vascular Balloon-Expandable Stent System.	July 31, 2012.
P040024/S056, FDA–2012–M–0968.	Medicis Aesthetics Holdings, Inc.	Restylane L Injectable Gel	August 30, 2012.
P110006, FDA–2012–M–1011.	U-Systems, Inc	somo-v® Automated Breast Ultrasound System (ABUS).	September 18, 2012

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: December 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00004 Filed 1–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1205]

Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Request for Comments

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 ''Accessible Standardized Medical Device Labeling.'' The purpose of this public workshop is to discuss the growing need for medical device labeling to be delivered in a clear, concise, and readily accessible format so that patients, caregivers, and healthcare providers may access and utilize device labeling as efficiently and effectively as possible. This public workshop aims to engage stakeholders in active discussion with FDA and to encourage public comments regarding standard content and format for medical device labeling and the use of a repository containing medical device labeling.

DATES: The public workshop will be held on April 29, 2013, from 8 a.m. to 5 p.m. and April 30, 2013, from 8 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting 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.*

FOR FURTHER INFORMATION CONTACT: Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5426, 301–796–6089, FAX: 301–847–8510, email: *Mary.Brady@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by April 5, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines by email: *Joyce.Raines@fda.hhs.gov* or phone: 301–796–5709 at least 7 days prior to the public 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 Mary Weick-Brady to register (see **FOR FURTHER INFORMATION CONTACT**). 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 April 5, 2013, 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 April 5, 2013. 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 a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to present during a public comment session and which topics you want to address. All topic-focused sessions will be held

during the general session. Standard content and format of full labeling and a shortened version of labeling will be addressed on the first day. The labeling repository will be discussed in a focused session on the second day. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 12, 2013. All requests to make oral presentations must be received by the close of registration on April 5, 2013, at 5 p.m. If selected for presentation, any presentation materials must be emailed to Mary Weick-Brady (see **FOR FURTHER INFORMATION CONTACT**) no later than March 29, 2013. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on medical device labeling. 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 April 12, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or 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. 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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).

I. Background

Currently, there are no regulations that explicitly define and describe a standard content and format for medical device labeling. FDA is concerned that the lack of standard content and format may translate into an increased risk of medical device error. Also, there is no single available source of medical device labeling for people to view, search, and download for devices that are used in clinical and non-clinical environments. FDA is aware of and concerned with the risk of medical errors that result from lost or inaccessible labeling.

FDA conducted a two-phase research study with Research Triangle Institute (RTI) focusing on healthcare professionals and their experiences with medical device labeling, and what they would want in a standard version of device labeling. Key findings from the survey helped create an outline for standard content and format for medical device labeling identifying the most relevant sections. Participants also expressed the need for a condensed version of labeling to act as a quick reference for safe and effective use of devices. Participants indicated that having a ''quick guide'' describing proper device operation and use would be more convenient and effective with the option of referring to a more comprehensive form of labeling should it be required.

FDA also conducted a survey with the National Family Caregivers Association (NFCA) on medical device labeling to elicit home caregivers' experiences with medical device labeling for devices that are used in the home. Respondents indicated what sections of medical device labeling they believed would be most important when operating or troubleshooting a device in the home care environment. Respondents also stated they would like a standard content and format of labeling with access to a ''quick guide'' for proper instructions for use. The majority of respondents stated they would make use of a searchable Web site that contained labeling for medical devices.

Accessible labeling has been a growing problem for healthcare professionals who operate medical devices, lay caregivers, and patients themselves. As more medical devices migrate out of clinical care environments and into patients' homes, the assurance that devices are being used properly and safely no longer resides with a healthcare professional; rather, the responsibility is with the patient, spouse, sibling, or even children. When medical devices are sent home with patients or are moved from one location to another, the labeling often becomes misplaced, lost, damaged, or discarded, which may result in adverse events or other complications due to misinterpretations and absence of proper labeling.

FDA is holding this public workshop to address these growing concerns and to solicit responses from the medical devices industry, healthcare practitioners, caregivers, and patients regarding a standard content and format of medical device labeling and methods to make medical device labeling accessible and searchable while keeping patient safety a priority.

II. Topics for Discussion at the Public Workshop

The workshop sessions will focus on the following general topics:

A. Summary of FDA Work on Labeling

1. RTI two-phase research study of healthcare professionals regarding device labeling.
2. NFCA survey of consumers on medical device labeling.
3. Cooperative Research and Development Agreement with Kwikpoint for the development of visual language for device labeling.
4. The Center for Drug Evaluation and Research measures of success with standard labeling and the use of a drug repository.

B. Standard Content and Format of Device Labeling

1. Review the outline for a draft standard content and format of medical device labeling.
2. Current thinking on a standard content and format of medical device labeling.
3. Use of symbols in medical device labeling.
4. Discuss a shortened version of standard medical device labeling.

C. Repository of Medical Device Labeling for Home Use Devices

1. Online access to device labeling.

2. Panel discussions on using an online device labeling site.

3. Discuss the types of devices whose labeling should be on the site.

Dated: December 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00003 Filed 1–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

Summary: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Bureau of Health Professions (BHPr) Performance Data Collection (OMB No. 0915–0061)—Revision

Abstract: Over 40 BHPr programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance training, and to strengthen the distribution of the health workforce. Many of these programs are governed by the Public Health Service Act (42 U.S.C. 201 *et seq.*), specifically Titles III, VII, and VIII. Performance information is collected in the HRSA Performance Report for Grants and Cooperative Agreements (PRGCA). Data collection activities at application, progress, and annual performance satisfy statutory and programmatic requirements for performance measurement and evaluation (including specific Title III, VII, and VIII requirements), as well as Government Performance and Results Act (GPRA) requirements. The Affordable Care Act impacted a broad range of health workforce programs administered by BHPr. It reauthorized many of these programs and, in some cases, expanded eligibility, modified program activities, and/or established new requirements. The Affordable Care Act also created new health professions programs. Therefore, it was necessary to reexamine BHPr's existing performance measures to ensure that they address these changes, meet evolving program management needs, and respond to emerging workforce concerns.

The purpose of the proposed revised data collection is to enhance analysis and reporting of grantee training activities and education, identify intended practice locations, and report outcomes of funded initiatives. Data collected from these grant programs will also provide a description of the program activities of more than 1,600 reporting grantees to better inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The proposed measures focus on five key outcomes: (1) Increasing the workforce supply of diverse well-educated practitioners, (2) influencing the distribution of practitioners to practice in underserved and rural areas, (3) enhancing the quality of education, (4) diversifying the pipeline for new health professionals, and (5) supporting educational infrastructure to increase the capacity to train more health professionals.

Revisions to the current reporting will require the collection of baseline data at the grant application and award stages and will include improved performance reporting at three levels of measurement: individual-level, program-specific, and program cluster-level.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Application	2,500	1	2,500	8	20,000
Program Aggregate Data Collection *	500	1	500	10	5,000
Individual-level Data Collection	800	1	800	5	4,000
Total					29,000

* Program aggregate data collection will only be required for programs that do not provide direct financial support to students.