TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Revalidation—820.75(c)	25,986	1	25,986	1	25,986
Acceptance activities—820.80(a) to (e)	25,986	1	25,986	5	129,930
Acceptance status—820.86	25,986	1	25,986	1	25,986
Control of nonconforming product—820.90(a)	25,986	1	25,986	5	129,930
Nonconforming product review/disposition procedures and rework procedures—820.90(b)(1) to (b)(2)	25,986	1	25,986	5	129,930
Procedures for corrective/preventive actions—820.100(a)(1) to (a)(7)	25,986	1	25,986	12	311,832
Corrective/preventive activities—820.100(b)	25,986	1	25,986	1	25,986
Labeling procedures—820.120(b)	25,986	1	25,986	1	25,986
Labeling documentation—820.120(d)	25,986	1	25,986	1	25,986
Device packaging—820.130	25,986	1	25,986	1	25,986
Handling—820.140	25,986	1	25,986	6	155,916
Storage—820.150(a) and (b)	25,986	1	25,986	6	155,916
Distribution procedures and records—820.160(a) and (b)	25,986	1	25,986	1	25,986
Installation—820.170	25,986	1	25,986	2	51,972
Record retention period—820.180(b) and (c)	25,986	1	25,986	2	51,972
Device master record—820.181	25,986	1	25,986	1	25,986
Device history record—820.184	25,986	1	25,986	1	25,986
Quality system record—820.186	25,986	1	25,986	1	25,986
Complaint files—820.198(a), (c), and (g)	25,986	1	25,986	5	129,930
Servicing procedures and reports—820.200(a) and (d)	25,986	1	25,986	3	77,958
Statistical techniques procedures and sampling plans—820.250	25,986	1	25,986	1	25,986
Total					9,043,128

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18351 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Steatohepatitis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research in cosponsorship with the American Association for the Study of Liver Diseases (AASLD) is announcing a 2-day public workshop entitled ''Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic fatty liver disease (NAFLD).'' There are no approved treatments for NAFLD and its complications of nonalcoholic steatohepatitis (NASH) and liver fibrosis and cirrhosis. This workshop will provide a forum to discuss trial design, including endpoints for clinical trials in NAFLD, to promote efficient drug development in this area and thus improved treatments for patients.

Date and Time: The public workshop will be held on September 5 and 6, 2013, from 8 a.m. to 5 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, in the Great Room (room 1503), 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.*

Contact Person: Anissa Davis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5016, FAX: 301–796–9904, email: *Anissa.Davis@fda.hhs.gov.*

Registration: There is no fee to attend the public workshop, but attendees must register online at *http://www.aasld.org/additionalmeetings/Pages/aasldfdanash.aspx* before September 1, 2013. (FDA has verified this Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Space is limited, and registration will be on a first-come, first-served basis. Those without Internet access should contact Anissa Davis (see *Contact Person*) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Anissa Davis (see *Contact Person*) at least 7 days in advance.

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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. 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.

SUPPLEMENTARY INFORMATION: This workshop will provide a forum to discuss the key issues in the design of clinical trials of drugs for the treatment of liver disease secondary to NAFLD. Stakeholders, including industry sponsors, those from academia, patients with NAFLD-associated liver disease, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in clinical trials. Trial design strategies and possible candidates for endpoints will be explored. The state of knowledge of the natural history of NAFLD will also be discussed.

Dated: July 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Requirements and Registration for ''Care Counts: Educating Women and Families Challenge''

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

Award Approving Official: Mary K. Wakefield, Ph.D., R.N., Administrator, Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration's (HRSA) Office of Women's Health, located within the Department of Health and Human Services (HHS), and in collaboration with the HHS Office on Women's Health, announces the launch of the Care Counts: Educating Women and Families Challenge.

Women are often at the center of healthy and resilient families; they make approximately 80 percent of all family health care decisions and are more likely to be the primary caregivers for children and elderly parents. To help make women aware of the important benefits available to them and their families through the Affordable Care Act, HHS is initiating this Challenge.

The Affordable Care Act is already making a difference in the lives of millions of Americans. Starting October 1, 2013, millions of uninsured Americans will be able to find affordable health insurance that meets their needs at the new Health Insurance Marketplace (Marketplace). The Marketplace is a one stop shop where people can learn about health insurance, get accurate information on different plans, and make apples-to-apples comparisons of private insurance plans. For the first time, comprehensive information about benefits and quality, side-by-side with facts about price, will help each consumer make the best coverage decision. For more information about how the Marketplace will work, including important deadlines and milestones, visit HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish).

This Challenge will allow teams (the ''Contestants'') to create innovative, educational tools (''Tools'') to inform women consumers, particularly women living in medically underserved communities, about enrollment in new health plans, as well as key provisions of the Affordable Care Act to improve their own health and that of their families.

For purposes of this Challenge, the key provision of the Affordable Care Act is coverage of 22 preventive services for women without copayment. See *https://www.healthcare.gov/what-are-my-preventive-care-benefits#part=2.*

The Tool must refer to *two or more* of the 22 covered preventive services for women. The Tool must also direct consumers to HealthCare.gov (English) or CuidadoDeSalud.gov (Spanish), and the toll-free Centers for Medicare and Medicaid (CMS) call centers (1–800–318–2596) (English and Spanish) to promote enrollment in the Marketplace. The Tool must also include the TTY/TTD call center number (1–888–871–6594).

The Tool may be designed to be used within systems of health care. For purposes of this Challenge, a system of health care is defined as the organization of people, institutions, and resources to deliver comprehensive culturally competent, quality, services to meet the health needs of the target audience. Examples include HRSA's Community Health Centers, Healthy Start programs, Ryan White Care service sites, National Health Service Corps sites, and HHS-supported Title X service sites. The Tool may also be designed to be used in community-based settings where women live, work, and purchase goods and services, such as schools, faith-based settings, recreation centers, and shopping centers.

''Tools'' are defined as print, web, or other social media (including Facebook, Twitter, Google+, Apps, and/or other innovative resources) used to educate the target audience to improve knowledge and abilities leading to action. The target audience for the Tools is adult women in the United States and its territories, particularly women living in medically underserved communities or who experience difficulty accessing health care. The Tools shall focus on communicating complex information in understandable, culturally competent, and relevant ways. Reading level, common language, and health literacy of the target audiences should be considered in development of the Tools.

Contestants must also submit a Promotion/Outreach Plan for the tools. The Promotion/Outreach Plan shall: (1) Be no more than two pages in length; (2) demonstrate the Contestants' understanding of the target audience; and (3) demonstrate how they will use the Tools to reach the target audience.