attending, and if participating via webcast or in-person.

Webcast Public Participation: After pre-registration, individuals participating by webcast will receive webcast access information via email.

In-Person Public Participation and Building Access: For in-person participants, the meetings are within the National Institutes of Health (NIH) Clinical Center (Building 10) as noted above in the Addresses section. Details regarding registration capacity and directions will be posted on *www.DietaryGuidelines.gov.* For in-person participants, check-in at the registration desk onsite at the meeting is required and will begin at 7:30 a.m. each day.

Public Comments and Meeting Documents: Written comments from the public will be accepted throughout the Committee's deliberative process; opportunities to present oral comments to the Committee will be provided at a future meeting. Written public comments can be submitted and/or viewed at *www.DietaryGuidelines.gov* using the ''Submit Comments'' and ''Read Comments'' links, respectively. Written comments received by June 5, 2013 will ensure transmission to the Committee prior to this meeting. Documents pertaining to Committee deliberations, including meeting agendas, summaries, and transcripts will be available on *www.DietaryGuidelines.gov* under ''Meetings'' and meeting materials will be available for public viewing at the meeting. Meeting information, thereafter, will continue to be accessible online, at the NIH Library, and upon request at the Office of Disease Prevention and Health Promotion, OASH/HHS; 1101 Wootton Parkway, Suite LL100 Tower Building; Rockville, MD 20852: Telephone (240) 453–8280; Fax: (240) 453–8281.

Dated: May 24, 2013.

Richard Olson,

Designated Federal Officer, Director, Division of Prevention Science, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.

[FR Doc. 2013–12859 Filed 5–24–13; 4:15 pm]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) announce the following meeting of the aforementioned committee:

Times and Dates: 8:00 a.m.–5:30 p.m., June 18, 2013; 8:00 a.m.–2:30 p.m., June 19, 2013.

Place: CDC Corporate Square, Building 8, Conference Room 1–ABC, 8 Corporate Boulevard, Atlanta, Georgia 30329, Telephone: (404) 639–8317.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people. This meeting is also accessible by teleconference. Toll-free +1 (866) 718–4584, Participant code: 8484551.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 100 people.

Purpose: This Committee is charged with advising the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, Viral Hepatitis and other STDs.

Matters To Be Discussed: Agenda items include: (1) STD clinical preventive services in primary care setting and integrating STD screening and treatment services in HIV care settings); (2) The test and cure era for hepatitis C: The public health response to rising hepatitis C mortality; The impact of new therapies on health outcomes; and Building care capacity to increase access to hepatitis C virus (HCV) therapy; (3) HIV Medical Monitoring Project: follow up on Institute of Medicine (IOM) report and other Affordable Care Act (ACA) issues; (4) Recommendations for new HIV diagnostic laboratory testing algorithms; and (5) CHAC Workgroups Update.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Margie Scott-Cseh, Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, 1600 Clifton Road NE., Mailstop E–07, Atlanta, Georgia 30333, Telephone (404) 639–8317.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–12857 Filed 5–29–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0577]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the requirements for the submission of labeling for human prescription drugs and biologics in electronic format.

DATES: Submit either electronic or written comments on the collection of information by July 29, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format—(OMB Control Number 0910–0530)—Extension

FDA is requesting that OMB extend approval under the Paperwork Reduction Act (44 USC 3501–3520) for the information collection resulting from the requirement that the content of labeling for prescription drug products be submitted to FDA electronically in a form that FDA can process, review, and archive. This requirement was set forth in the final rule entitled ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (December 11, 2003; 68 FR 69009), which amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs) (21 CFR 314.50(l)(1)(i)), including supplemental NDAs, abbreviated new drug applications (ANDAs) (21 CFR 314.94(d)(1)(ii)), including supplemental ANDAs, and annual reports (21 CFR 314.81(b)(2)(iii)(*b*)) (the final rule also applied to certain BLAs, but the information collection for these requirements is not part of this OMB approval request).

This OMB approval request is only for the burden associated with the electronic submission of the content of labeling. The burden for submitting labeling as part of NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports, has been approved by OMB under control number 0910–0001.

We estimate that it should take applicants approximately 1.25 hours to convert the content of labeling from Word or PDF to structured labeling format (SPL) format. The main task involved in this conversion is copying the content from one document (Word or PDF) to another (SPL). Over the past few years, several enhancements have been made to SPL authoring software which significantly reduces the burden and time needed to generate well-formed SPL documents. SPL authors may now copy a paragraph from a Word or PDF document and paste the text into the appropriate section of an SPL document. In those cases where an SPL author needs to create a table, the table text may be copied from the Word or PDF document and pasted into each table cell in the SPL document, eliminating the need to retype any information. Enhancements have also been made to the software for conversion vendors. Conversion software vendors have designed tools which will import the Word version of the content of labeling and, within minutes, automatically generate the SPL document (a few formatting edits may have to be made).

Based on the number of content of labeling submissions received during the past few years, we estimate that approximately 5,750 content of labeling submissions are made annually with original NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports by approximately 500 applicants. Therefore, the total annual hours to convert the content of labeling from Word or PDF to SPL format would be approximately 7,187.50 hours.

Concerning costs, we conclude that there are no capital costs or operating and maintenance costs associated with this collection of information. In May 2009, FDA issued a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.'' The guidance describes how to electronically create and submit SPL files using defined code sets and codes for establishment registration and drug listing information, including labeling. The information collection resulting from this guidance, discussed in the **Federal Register** of January 8, 2009 (74 FR 816), has been approved by OMB under control number 0910–0045. As discussed in the January 8, 2009, **Federal Register** notice, to create an SPL file and submit it to FDA, a registrant would need the following tools: A computer, appropriate software, access to the Internet, knowledge of terminology and standards, and access to FDA's electronic submission gateway (ESG). Registrants (and most individuals) have computers and Internet access available for their use. If a business does not have an available computer or access to the Internet, free use of computers and the Internet are usually available at public facilities, e.g., a community library. In addition, there should be no additional costs associated with obtaining the appropriate software. In 2008, FDA collaborated with GlobalSubmit to make available free SPL authoring software that SPL authors may utilize to create new SPL documents or edit previous versions. (Information on obtaining this software is explained in section IV.A of the guidance ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Listing.'') In addition to the software, FDA also provides technical assistance and other resources, code sets and codes, and data standards regarding SPL files.

After the SPL file is created, the registrant would upload the file through the ESG, as explained in the January 8, 2009, **Federal Register** notice. A digital certificate is needed to use the ESG. The digital certificate binds together the owner's name and a pair of electronic keys (a public key and a private key) that can be used to encrypt and sign documents. A fee of up to $20.00 is charged for the digital certificate and the registrant may need to renew the certificate not less than annually. We are not calculating this fee as a cost for this extension because all applicants who submit content of labeling are also subject to the drug establishment registration and listing requirements and would have already acquired the digital certificate as a result of the May 2009 guidance on drug establishment registration and listing.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Content of labeling submissions in NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports	Number of respondents	Number of responses per response	Total annual responses	Average burden per response	Total hours
	500	11.50	5,750	1.25	7,187.50

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

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12825 Filed 5–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0495]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 1, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study on Consumer Responses to Nutrition Facts Labels with Various Footnote Formats and Declaration of Amount of Added Sugars—(OMB Control Number 0910–New)

I. Background

Under the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535), the Nutrition Facts label is required on most packaged foods and this information must be provided in a specific format in accordance with the provisions of § 101.9 (21 CFR 101.9). When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 to 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in the **Federal Register** of November 2, 2007 (72 FR 62149), FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) entitled, ''Food Labeling: Revision of Reference Values and Mandatory Nutrients'' (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels. In the 2007 ANPRM, the Agency included a request for comments on how consumers use the percent Daily Value in the Nutrition Facts label when evaluating the nutritional content of food items and making purchases.

Research has suggested that consumers use the Nutrition Facts label in various ways, including, but not limited to, using the Nutrition Facts label to determine if products are high or low in a specific nutrient and to compare products (Ref. 6). One component of the Nutrition Facts label that serves as an aid in these uses is the percent Daily Value. Early consumer research indicated that the percent Daily Value format improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (Ref. 3), which led FDA to require both quantitative and percentage declarations of nutrient Daily Values in the Nutrition Facts label in the 1993 Nutrition Labeling final rule (58 FR 2079, January 6, 1993).

Research in subsequent years, however, suggested that consumers' understanding and use of percent Daily Value may be somewhat inconsistent (Refs. 7 and 8). Additionally, FDA has received several public comments suggesting that further research on percent Daily Values may be warranted, along with research on other modifications to the Nutrition Facts label. Suggested research on potential modifications includes research on: (1) The removal of the statements, ''Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs''; (2) the removal of the table in the footnote that lists the Daily Values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets as described in § 101.9(d)(9); and (3) changes to the presentation of and amount of information provided in the Nutrition Facts label. Therefore, the FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to various food label formats for the footnote area of the Nutrition Facts label, including those that exhibit information such as a description of percent Daily Value, a succinct statement about daily caloric intake, a general guideline for interpreting percent Daily Values, or a footnote about nutrients whose daily intake should be limited.

This study will also explore how declaring the added sugars content of foods might affect consumers' attention to and understanding of the sugars and calorie contents and other information on the Nutrition Facts label. FDA received numerous comments regarding the declaration of added sugars in response to the 2007 ANPRM even though the Agency did not ask any