ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
	Main Interview	2400	1	40/60	1600
Total					1750

Dated: October 22, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–25911 Filed 10–27–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–10–0017]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Application for Training (OMB No. 0920–0017 exp. 3/31/2010)—Revision—Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

OWCD requests an additional three years to continue CDC's and the Agency for Toxic Substances and Disease Registry's (ATSDR's) use of the training application forms described below.

CDC offers public health training activities to professionals worldwide. Employees of hospitals, universities, medical centers, laboratories, State and Federal agencies, and State and local health departments apply for training to learn up-to-date public health practices. CDC's training activities include laboratory training, classroom study, online training, and distance learning.

CDC uses training application forms to collect information necessary to manage and conduct training pertinent to the agency's mission. This information allows CDC to send confirmation of registration to participants, provide certificates of attendance or continuing education credits as proof of participants' attendance, and generate management reports to identify training needs, design courses, select location for courses, and evaluate programs.

CDC is accredited by six different continuing education (CE) organizations to award CE credit: (1) The International Association for Continuing Education and Training (IACET) to provide Continuing Education Units (CEUs), (2) the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education credits (CME), (3) the American Nurses Credentialing Center (ANCC) to provide Continuing Nurse Education credits (CNE), (4) the National Commission for Health Education Credentialing (NCHEC) to award CHES credit, (5) the Accreditation Council for Pharmacy Education (ACPE) to provide continuing pharmacy credit, and (6) the American Association of Veterinary State Boards to award Registry of Approved Continuing Education (RACE) credit. The accrediting organizations require a method of tracking participants who complete an educational activity, and demographic data allows CDC to do so. Also, several of the organizations require a permanent record that includes the participant's name, address, and phone number, to facilitate retrieval of historical information about when a participant completed a course or several courses during a time period. This information provides the basis for a transcript or for determining whether a person is enrolled in more than one course. CDC uses the e-mail address to verify the participant's electronic request for transcripts, verify course certificates, and send confirmation a participant is registered for a course.

CDC uses the information on the training application forms request to (1) grant public health professionals the CE credits they need to maintain professional licenses and certifications, (2) create a transcript or summary of training at the participant's request, (3) generate management reports, and (4) maintain training statistics. Management reports help CDC identify training needs, design courses, select locations for courses, evaluate programs, and conduct impact analysis.

Tracking course attendance and meeting accrediting organizations' standards for reporting, require uniform standardized training application forms. The standardized data these forms request for laboratory training, classroom study, online training, and distance learning are not requested elsewhere. In other words, these forms do not duplicate requests for information from participants. Data are collected only once per course or once per new registration.

The annual burden table has been updated to reflect an increase in distance learning. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Forms	Respondent type	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden hours
Application for Training	Laboratorians, Doctors, Nurses	74,000	1	5/60	6167
Total					6167

Dated: October 22, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0355]

Draft Guidance for Industry and Reviewers on Structured Product Labeling Standard for Content of Labeling Technical Questions and Answers, Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for industry and reviewers entitled ''SPL Standard for Content of Labeling Technical Qs & As.'' This draft guidance is intended to assist sponsors who submit the content of their product labeling to the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) using the Structured Product Labeling standard (SPL) in extensible markup language (XML). The draft guidance also provides information to CDER and CBER staff who review and manage that product information using electronic systems. This draft guidance is being revised to reflect technological changes and changes resulting from the requirement in the Food and Drug Administration Amendments Act of 2007 to submit drug establishment registration and drug listing information electronically.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by December 28, 2009. Submit electronic or written comments on the collection of information by December 28, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. All comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lonnie Smith, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0011.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published final regulations requiring that the content of labeling be submitted to FDA electronically for new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and annual reports (see 21 CFR 314.50(l), 314.94(d), 601.14(b), and 314.81(b), respectively) (the December 2003 regulations). The December 2003 regulations state that the content of labeling must be submitted to FDA electronically and ''in a form that FDA can process, review, and archive.''

Initially, CDER accepted electronic submissions of content of labeling in portable document format (PDF). Then, in September 2004, CDER announced that it would accept content of labeling in both PDF and SPL formats until the autumn of 2005. On October 21, 2005, CDER announced that effective October 31, 2005, CDER would no longer accept content of labeling submissions in PDF format and that applicants should use the SPL standard when submitting content of labeling to FDA in XML with original submissions, supplements, and annual reports. CBER made a similar announcement on July 11, 2008, which went into effect on October 15, 2008. On July 10, 2008, CDER, CBER, and the Center for Veterinary Medicine announced their intention to begin using the SPL standard for electronic drug establishment registration and drug product listing.

Since FDA began accepting content of labeling in SPL format for application submissions, we have received numerous questions about SPL submission requirements. Based on preliminary questions, and in an effort to provide easy access to common questions that were being raised, in December 2005 we published a final guidance for industry entitled ''SPL Standard for Content of Labeling Technical Qs and As.'' As a result of initial experience using the SPL format and as a result of changes to the system for receiving registration and listing information, FDA is revising its SPL Qs & As guidance to provide recommendations in response to additional technical questions. Because of the number of questions that have arisen as a result of the actions described in this section of the document, FDA is issuing this guidance as a draft to solicit input from the public on the recommendations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on submitting content of labeling in the SPL format. It does not create or confer