the DailyMed, a new way to distribute up-to-date and comprehensive medication information in a computerized format for use in health care information systems.

Because FDA's current procedures using PDF are not adequate to support these initiatives, the agency is changing the way it processes, reviews, and archives the content of labeling. We are adopting a new technology for exchanging information between computer systems developed by Health Level Seven (HL7), a standards development organization accredited by the American National Standards Institute. The new technology, based on Clinical Document Architecture (CDA), allows information to be exchanged in extensible markup language (XML) and is the standard being investigated for the EHR. FDA, working with other parties in HL7 (experts from HL7, industry, and technology solution providers), has adapted CDA for labeling in an HL7 standard called Structured Product Labeling (SPL).

FDA is developing an automated system using SPL for processing and managing labeling and labeling changes. FDA's Center for Drug Evaluation and Research has identified SPL in public docket number 1992S–0251 as a format that FDA can use to process, review, and archive the content of labeling. During our transition to the automated system, the agency is able to accept the content of labeling in either PDF or SPL file format. After the automated system is implemented, PDF will no longer be a format that we can use to process, review, and archive the content of labeling. At this time, it is our goal to complete the transition to SPL format for content of labeling submissions by fall 2005.

In the **Federal Register** of February 5, 2004 (69 FR 5552), FDA published a document announcing the availability of a draft guidance for industry and gave interested persons an opportunity to submit comments by April 5, 2004. Based on comments received on the draft guidance, the agency has taken the following actions:

- Lengthened the timeframe for the agency's implementation of the automated system using SPL;
- Developed a Web site (on the Internet at *http://www.fda.gov/oc/datacouncil/spl.html*) to provide technical support for the transition to SPL, including links to SPL-related documents and resources, stylesheet files for viewing SPL files, and example labels; and
- Revised the guidance to clarify the procedures for submitting content of labeling in electronic format.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing the content of labeling in electronic format as required in 21 CFR parts 314 and 601. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control number 0910–0530, expiring November 30, 2006.

V. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 15, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7946 Filed 4–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Loan Repayment; Submission for OMB Review; Comment Request; National Institutes of Health Loan Repayment Programs

Summary: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Loan Repayment, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 10, 2004, and allowed 60 days for public comment. No responses to the notice were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number. The programs have existing data collections with an OMB control number (OMB No. 0925–0361, expiration date 12/31/2004). An extension has been granted until March 2005 due to an administrative delay caused by a change in office responsible for the LRPs.

Proposed Collection

Title: National Institutes of Health Loan Repayment Programs.

Type of Information Collection Request: Revision of a currently approved collection (OMB No. 0925–0361, expiration date 12/31/04, extension granted until 03/05).

Form Numbers: NIH 2674–1, NIH 2674–2, NIH 2674–3, NIH 2674–4, NIH 2674–5, NIH 2674–6, NIH 2674–7, NIH 2674–8, NIH 2674–9, NIH 2674–10, NIH 2674–11, NIH 2674–12, NIH 2674–13, NIH 2674–14, NIH 2674–15, NIH 2674–16, NIH 2674–17, NIH 2674–18, and NIH 2674–19.

Need and Use of Information Collection: The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm. D., D.D.S., D.M.D., D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or biobehavioral research in NIH intramural laboratories or who perform research that is supported by a domestic non-profit institution or a U.S. Government (Federal, state, local) entity for a minimum of 2 years (3 years for the General Research LRP) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS–LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288–1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP) is authorized by Section 487E (42 U.S.C.

288–5); the General Research Loan Repayment Program (GR–LRP) is authorized by Section 487C of the Public Health Service Act (42 U.S.C. 288–3); the Loan Repayment Program Regarding Clinical Researchers (LRP–CR) is authorized by Section 487F (42 U.S.C. 288–5a); the Pediatric Research Loan Repayment Program (PR–LRP) is authorized by Section 487F (42 U.S.C. 288–6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR–LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288–5); the Contraception and Infertility Research LRP (CIR–LRP) is authorized by Section 487B (42 U.S.C. 288–2); and the Health Disparities Research Loan Repayment Program (HD–LRP) is authorized by Section 485G (42 U.S.C. 287c–33).

The Loan Repayment Programs can repay up to $35,000 per year toward a participant's extant eligible educational loans, directly to lenders, in addition to salary and benefits. The information proposed for collection will be used by the Office of Loan Repayment to determine an applicant's eligibility for participation in the program.

Frequency of Response: Initial application and annual renewal application.

Affected Public: Applicants, financial institutions, recommenders, and advisors.

Type of Respondents: Physicians, other scientific or medical personnel, and institutional representatives. The annual reporting burden is as follows:

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
Intramural LRPs:				
Initial Applicants	75	1	8.98	673.50
Recommenders	225	1	0.38	85.50
Financial Institutions	8	1	0.33	2.64
Subtotal	308			761.64
Extramural LRPs:				
Initial Applicants	1,600	1	10.30	16,480.00
Recommenders	4,800	1	0.38	1,824.00
Advisors/Supervisors	1,600	1	1.15	1,840.00
Financial Institutions	160	1	0.33	52.80
Subtotal	8,160			20,196.880
Extramural LRPs:				
Renewal Applicants	800	1	7.81	6,248.00
Recommenders	2,400	1	0.38	912.00
Advisors/Supervisors	800	1	1.15	920.00
Subtotal	4,000			8,080.00
Total	12,468			29,038.44

The annualized cost to respondents is estimated at $996,420.66. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Alfred C. Johnson, Ph.D., Deputy Director, Office of Loan Repayment and Scholarship, National Institutes of Health, 6011 Executive Blvd, Room 206 (MSC 7650), Bethesda, Maryland 20892–7650. Dr. Johnson can be contacted via e-mail at *JohnsoA1@od.nih.gov* or by calling 301–402–6425.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 12, 2005.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

[FR Doc. 05–8003 Filed 4–20–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.