Rockville Pike, Rockville, MD 20852, 301–827–0373, e-mail: *robert.yetter@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

During the past decade, FDA has been working to expand its ability to receive and review marketing applications electronically. In addition, the agency has been working through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to harmonize the formats being used for marketing applications.

Beginning in 1999, FDA issued two guidances and one draft guidance for industry that made recommendations to applicants wishing to submit applications to FDA in electronic format: (1) ''Providing Regulatory Submissions in Electronic Format—NDAs'' (e-NDA guidance) (64 FR 4432, January 28, 1999), (2) ''Providing Regulatory Submissions in Electronic Format—ANDAs'' (e-ANDA guidance) (67 FR 43331, June 27, 2002), and (3) ''Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications'' (draft) (68 FR 51788, August 28, 2003). In general, these guidances recommended submitting documents as portable document files (PDF), electronic data/case report tabulations as SAS transport files, and the NDA table of contents in PDF format. In the meantime, however, the FDA adopted the ICH Common Technical Document (CTD) headings and subheadings for marketing applications. ICH then issued specifications for the electronic version of the CTD (e-CTD).

In October 2005, FDA issued the guidance ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the e-CTD Specifications'' (the e-CTD guidance) (70 FR 60842; October 19, 2005). This guidance differs from the e-NDA and e-ANDA guidances in one significant aspect: The application table of contents is no longer submitted as a PDF file, but is submitted as an XML (extensible markup language) file. This XML file has numerous advantages over the older PDF format, most significant of which is the ability to update the application table of contents automatically as new amendments are received. With the e-CTD format, sponsors and reviewers now have access to a real-time, up-to-date, cumulative table of contents that provides easy and immediate access to all files included in an application, regardless of when they were included, or in what submission they are located. This has never previously been possible. Another advantage is that the table of contents can be displayed in various ways, allowing discipline-specific views of an application, further promoting review efficiency. This is especially important for agency review staff. For example, although all portions of an application are always available to all reviewers, a chemist would be interested in different portions of the application than a clinical reviewer. The XML table of contents permits reviewers to view the application in a manner that makes the most sense to support their particular review activity.

Despite the release of the e-CTD guidance describing the use of the XML format, FDA has continued to make all three guidances available with their differing recommendations. As a result, applicants have had three choices when submitting a marketing application electronically: (1) Use the e-NDA/e-ANDA format, (2) use the e-CTD format, or (3) use what we call a ''hybrid'' submission (the older e-NDA format with the table of contents organized using the newer CTD headings). In addition, FDA still receives submissions that are a combination of paper and electronic formats. Of course, this would not be appropriate for sponsors who are using the e-CTD format, as doing this would negate the intent of having all portions of the application readily available for review via the XML table of contents. A result of having this variety of choices is confusion and frustration for industry, who are not receiving consistent recommendations about how to submit marketing applications. It is also confusing and frustrating for our review staff. In addition, our willingness to receive applications in a variety of different forms has forced the agency to maintain expensive and duplicative processes and systems for receiving and archiving these various application types.

II. Withdrawal of Guidances

The e-CTD format is preferred by FDA because it is more efficient than the other choices and consistent with FDA's technical capabilities. The e-CTD format is also the preferred ICH format. As a result, the agency is withdrawing the earlier guidances. In addition, we will remove references to these guidances from the electronic submissions docket on December 31, 2007. Further information on providing regulatory submissions in electronic format can be found on Docket No. 1992S–0251 (formerly Docket No. 92S–0251) (*http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm*). We are recommending that sponsors wishing to submit applications electronically use the most efficient and internationally agreed to formats recommended in our most recent guidance.

Although the Center for Biologics Evaluation and Research (CBER) supports the use of the e-CTD format and encourages its sponsors to use this format when creating its submissions, CBER also recognizes that in certain situations a sponsor may not be capable of providing submissions in that format at this time. Therefore, CBER recommends that sponsors who cannot use the e-CTD format consult guidance for industry ''Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA) / Establishment License Application (ELA) and New Drug Application (NDA)] (11/12/1999) (available online at *http://www.fda.gov/cber/esub/esubguid.htm*).

Dated: September 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–15966 Filed 9–28–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms (OMB No. 0915–0043 Extension)

The Health Education Assistance Loan (HEAL) program continues to administer and monitor outstanding

loans which were provided to eligible students to pay for educational costs in a number of health professions. HEAL forms collect information that is required for responsible program management. The HEAL Repayment Schedule, Fixed and Variable, provides the borrower with the cost of a HEAL loan, the number and amount of payments, and the Truth-in-Lending disclosures. The Lender's Report on HEAL Student Loans Outstanding (Call Report), provides information on the status of loans outstanding by the number of borrowers and total number of loans whose loan payments are in various stages of the loan cycle, such as student education and repayment, and the corresponding dollar amounts. These forms are needed to provide borrowers with information on the cost of their loan(s) and to determine which lenders may have excessive delinquencies and defaulted loans.

The estimate of burden for the forms is as follows:

Form and number	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Disclosure:					
Repayment Schedule HRSA 502–1,2	8	666	5,328	0.50	2,664
Reporting:					
Call Report HRSA 512	20	4	80	0.75	60
Total Reporting and Disclosure	28		5,408		2,724

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 22, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–15960 Filed 9–28–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

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, call the HRSA Reports Clearance Officer on (301) 443–1129.

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.

Proposed Project: Web-Based Semi Annual Report (SAR) (OMB No. 0915–0262)—Extension

The HRSA's Bureau of Primary Health Care (BPHC) collects the annual reporting requirements for the primary care grantees funded by BPHC using the Web-based Semi Annual Report (SAR). The SAR includes reporting requirements for grantees of the following primary care programs: State Primary Care Associations and State Primary Care Offices. Authorizing legislation is found in Section 330(m) of the Public Health Service Act, as amended.

BPHC collects data on its programs to ensure compliance with legislative mandates and to monitor and report on program accomplishments. To meet these objectives, BPHC requires a core set of information collected semi-annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The SAR has been a valuable instrument for collecting this information from grantees. The SAR provides data on services, characteristics of populations, leveraged funds, and services that fall within the scope of the grant.

Estimates of annualized burden are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
SAR	103	1	103	18	1,854