information about youth in the program. Finally, the study will include an administrative survey of grantees participating in the study. The proposed study will include baseline and follow-up surveys (to be administered approximately 12 months apart) of youth ages 9–16 in the MCP program and will compare changes in key behaviors for program youth against changes in behaviors of similar youth not enrolled in mentoring programs. By comparing changes for youth in the MCP program against changes for youth not in the program, we will be able to determine if MCP youths' behaviors are closer to the norm for their age group at follow-up than at program intake. If MCP youths' behaviors and outcomes are shown to improve relative to other groups, the MCP program has demonstrated the potential for positive impacts. The survey also will include some general informational questions about youth in the study so that HHS, policy makers, and practitioners can have a greater understanding of the life circumstances of these youth and of some of the challenges they may face.

The youth surveys will focus on measuring both attitudinal and behavioral changes in areas targeted by the MCP program including attitudes towards and performance in school; relationships with parents, peers and teachers; self-esteem; and engagement in a variety of risk behaviors, including alcohol and drug use and physical violence. They also will include questions about the living situations of youth in the study, their relationships with both incarcerated and non-incarcerated caregivers, and their relationships with other supportive adults in their communities.

The administrative survey of grantees will include questions about the programmatic structure of each grantee. It will provide information about variations in program administration, mentor activities, and youth served.

Respondents: The proposed study sample consists of a cohort of 625 youth ages 9–16 in MCP programs operated at 10 or more different program sites. Survey data will also be collected from approximately 72 grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Student Baseline Survey	625	1	.5	312.5
Student follow-up Survey	500	1	.5	250
Grantee Survey	72	1	1	72

Estimated Total Annual Burden Hours: 634.5

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 8, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–9666 Filed 12–12–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0104]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 January 12, 2007.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

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 PRA for the information collection contained in the final rule entitled ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (68 FR 69009, December 11, 2003) (the 2003 final rule). The 2003 final rule amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs), certain biological license applications (BLAs),

abbreviated new drug applications (ANDAs), supplements, and annual reports. The 2003 final rule required that the content of labeling for prescription drug and biological products required under 21 CFR 201.100(d)(3) be submitted to FDA electronically in a form that FDA can process, review, and archive. Copies of product labeling have been required to be submitted to FDA for review in NDAs, certain BLAs, ANDAs, certain supplements, and annual reports under §§ 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12 (21 CFR 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12). Under these regulations, copies of labeling may be submitted electronically or on paper. The 2003 final rule added the requirement to submit the content of labeling in electronic format to simplify the drug labeling review process and speed up the approval of labeling changes. The reporting burden for submitting labeling under §§ 314.50, 314.70, 314.81, 314.94, 314.97, and 314.98 has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001, most recently until May 31, 2008. The reporting burden associated with current §§ 601.2 and 601.12 has also been estimated and that collection of information has been approved by OMB under OMB control number 0910–0338, most recently until September 30, 2008. We are not re-estimating these approved burdens in this action. Only the additional reoccurring reporting burdens associated with the electronic submission of the content of labeling in the 2003 final rule are estimated in this action.

New NDAs (§ 314.50), ANDAs (§ 314.94), and BLAs (§ 601.2): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.50, 314.94, and 601.2, we estimate that approximately 75 NDA applicants, 160 ANDA applicants, and 6 BLA applicants (respondents) submit applications to us annually. We estimate that these applicants (respondents) submit approximately 111 NDAs, 766 ANDAs, and 21 BLAs each year that are subject to the requirements of the 2003 final rule. As explained in section V of the 2003 final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Supplements to NDAs (§ 314.70), ANDAs (§ 314.97), and BLAs (§ 601.12(f)(1) and (f)(2)): Based on the number of submissions during 2005 under the approved collections of information for § 314.70, § 314.97, and § 601.12(f)(1) and (f)(2), we estimate that approximately 272 NDA applicants, 189 ANDA applicants, and 35 BLA applicants (respondents) submit supplements to approved applications to us annually. We estimate that these applicants (respondents) submit approximately 1,839 NDA supplements, 3,208 ANDA supplements, and 82 BLA supplements each year that are subject to the requirements of the 2003 final rule. As explained in section V of the 2003 final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Annual Reports for NDAs (§ 314.81), ANDAs (§ 314.98), and BLAs (§ 601.12(f)(3)): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.81, 314.98, and 601.12(f)(3), we estimate that approximately 306 NDA applicants, 333 ANDA applicants, and 4 BLA applicants (respondents) submit annual reports to us annually. We estimate that NDA applicants submit to us approximately 2,617 annual reports, ANDA applicants submit approximately 6,054 annual reports, and BLA applicants submit approximately 16 annual reports each year that are subject to the requirements of the final rule. As explained in section V of the 2003 final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these submissions, will be less than 15 minutes.

In the **Federal Register** of March 29, 2006 (71 FR 15752), FDA published a 60-day notice requesting comments on the information collection provisions. FDA gave interested parties an opportunity to comment on the information collection during the process requesting that OMB extend approval of the collection. We received several comments. Generally, the comments said that, unlike FDA's 2003 final rule, the agency has now identified Extensible Markup Language (XML) as the required file format for Structured Product Label documents (SPL). The comments said that the March 29, 2006, **Federal Register** notice does not take into account the amount of time required to obtain, install, and update the program required to create the electronic files in the new format, and that SPL is a relatively new format requiring an initial investment in software, training, and process change that cannot simply be converted from the Word or PDF version of labeling. The comments said that the process for creating the SPL labeling includes significant effort in mapping, coding, recreation of the file, and quality control.

We appreciate the comments and believe they raise important issues. We will respond to the comments and amend this collection as soon as we have gathered sufficient information to address the costs specified in the comments. The public will have an opportunity to comment on our response at that time.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Applications					
314.50	75	1.48	111	.25	27.75
314.94	160	4.79	766	.25	191.50
601.14[2]	6	3.50	21	.25	5.25
Supplements					
314.70	272	6.76	1,839	.25	459.75
314.97	189	16.98	3,208	.25	802
601.14[3]	35	2.34	82	.25	20.5
Annual Reports					
314.81	306	8.55	2,617	.25	654.25
314.98	333	18.18	6,054	.25	1,513.50
601.14[4]	4	4	16	.25	4

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Total Reporting Burden Hours					3,678.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Applications submitted under § 601.2.
[3] Supplements submitted under § 601.12(f)(1) and (f)(2).
[4] Annual reports submitted under § 601.12(f)(3).

Dated: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21132 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0382]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

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 January 12, 2007.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Postmarket Surveillance—21 CFR Part 822 (OMB No. 0910–0449)—Extension

Section 522(a) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute.

The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 to 822.18 of the regulation, which describe the grounds for approving or disapproving a PS plan. If this information is not collected, FDA would not be able to ensure that the PS will result in the collection of useful data that could reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require PS of their products.

In the **Federal Register** of October 2, 2006 (71 FR 57973), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
822.9, 822.10	5	1	5	120	600
822.21	3	1	3	40	120
822.26	1	1	1	8	8
822.27	1	1	1	40	40
822.28	1	1	1	40	40
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.34	1	1	1	20	20
822.38	10	2	20	120	2,400
Total					3,338

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