but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan also must be submitted to ORI by the institution. Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2010–16824 Filed 7–8–10; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee.

Time and Date: July 19, 2010 9 a.m.–5 p.m. July 20, 2010 8:30 a.m.–5 p.m. July 21, 2010 9 a.m.–5 p.m. (committee discussion)

Place: Hamilton Crowne Plaza Hotel, 1001 14th Street, NW., Washington, DC 20005, (202) 682–0111.

Status: Open.

Purpose: The purpose of this upcoming meeting of the Subcommittee on Standards is to receive industry input on a unique health plan identifier to be used in HIPAA standard transactions, and on new operating rules for standards, and their authoring organizations. The Subcommittee will hear testimony from individuals, organizations and associations on these matters. The subcommittee will meet for three consecutive days for which a variety of panels are scheduled; day one will focus on the unique health plan identifier, day two will concentrate on authoring organizations and operating rules for eligibility and health claim status, and day three of the meeting will be reserved for Subcommittee discussion and deliberation.

The NCVHS has been named in the Patient Protection and Affordable Care Act (ACA) of 2010 to review and make recommendations on several HIPAA standards and electronic transactions. This meeting will support these activities in the development of a set of recommendations for the Secretary, as required by section 1104 of the ACA. Text of the ACA can be found at *http://dpc.senate.gov/dpcdoc-sen_health_care_bill.cfm.*

Contact Person For More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Lorraine Doo, lead staff for the Standards Subcommittee, NCVHS, Centers for Medicare and Medicaid Services, Office of E-Health Standards and Services, 7500 Security Boulevard, Baltimore, Maryland, 21244, telephone (410) 786–6597 or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: June 29, 2010.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2010–16729 Filed 7–8–10; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0174]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed

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 August 9, 2010.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0513. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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.

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed—OMB Control Number 0910–0513—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(1)) requires all new drug application (NDA) applicants to file, as part of the NDA, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug." Section 505(c)(2) of the act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the act, we publish patent information after approval of an NDA in the list entitled "Approved Drug Products With Therapeutic Equivalence Evaluations"

(the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

FDA regulations at §§ 314.50(h) and 314.53 (21 CFR 314.50(h) and 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement, and require persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Form FDA 3542a and Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or supplement in accordance with § 314.50(a) through (f) and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained in the following paragraphs, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Forms 3542 and 3542a, the required patent information described in this section.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, an amendment, or a supplement (collectively referred to as "application") the required patent declaration(s) on Form 3542a for each "patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method of use. If a patent is issued after the application is filed with FDA but before the application is approved, the applicant must submit the required patent information on Form 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use for listing in the Orange Book. In addition, for patents issued after the date of approval of an application, Form 3542 must be submitted within 30 days of the date of issuance of the patent.

In the **Federal Register** of April 8, 2010 (75 FR 17924), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information request.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section § 314.50 (citing § 314.53)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	233	2.6	606	20	12,120
Form FDA 3542	154	2.6	400	5	2,000
Total					14,120

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

The numbers of patents submitted to FDA for listing in the Orange Book in 2007, 2008, and 2009 were 268, 347, and 335, respectively, for an annual average of 317 (268 patents + 347 patents + 335 patents) / 3 years = 317 patents / year). Because many of these individual patents are included in multiple NDA submissions, there could be multiple declarations for a single patent. From our previous review of submissions, we believe that approximately 14 percent of the patents submitted are included in multiple NDA submissions, and thus require multiple patent declarations. Therefore, we estimate that 44 (317 patents x 14 percent) patents will be multiple listings, and there will be a total of 361 patents (317 patents + 44 patents = 361 patents) declared on Form FDA 3542. We approved 67, 73, and 77 NDAs in 2007, 2008, and 2009, respectively, of which approximately 71 percent submitted patent information for listing in the Orange Book. The remaining NDAs submitted Form 3542 as required and declared that there were no relevant patents. We also approved approximately 88, 96, and 62 NDA supplements in 2007, 2008, and 2009, respectively, for which submission of a patent declaration would be required. We estimate there will be 154 instances (based on an average of 72 NDA approvals and 82 supplement approvals per year) where an NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 2.6 declarations ((361 patent declarations + 45 no relevant patent declarations) / 154 instances = 2.6 declarations per instance) on Form FDA 3542. We filed 120, 113, and 118 NDAs in 2007, 2008, and 2009, respectively, and 145, 99, and 104 NDA supplements in 2007, 2008, and 2009, respectively, for which submission of a patent declaration would be required. We estimate there will be 233 instances (based on an average of 117 NDAs filed and 116 NDA supplements filed per year) where an NDA holder would be affected by the patent declaration requirements. We estimate, based on a proportional increase from the number of declarations for approved NDAs, that there will be an annual total of 606 declarations (233 instances x 2.6 declarations per instance = 606 declarations) on Form FDA 3542a submitted with these applications. Based upon information provided by regulated entities and other information, we previously estimated that the information collection burden associated with § 314.50(h) (citing § 314.53) and FDA Forms 3542a and 3542 will be approximately 20 hours and 5 hours per response, respectively.

On December 3, 2008, FDA announced in the **Federal Register** (73 FR 73659) the availability of a draft guidance for industry entitled

"Submission of Patent Information for Certain Old Antibiotics." That draft guidance, if finalized, would provide information regarding FDA's current thinking on the implementation of section 4(b)(1) of the Q1 Program Supplemental Funding Act (Public Law 110–379). Section 4(b)(1) of the Q1 Act requires submission to FDA of patent information by sponsors of certain NDAs containing old antibiotics. Estimates on the number of Forms FDA 3542a and 3542 that might be submitted in accordance with a finalized guidance have been included in table 1 of this document.

Dated: July 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16738 Filed 7–8–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

*Comments are invited on: (*a) Whether the proposed collections of information are 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: Voluntary Customer Satisfaction Surveys To Implement Executive Order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—(OMB No. 0930–0197)—Extension

Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/ respondent	Hours/ response	Total hours
Focus groups	250	1	2.50	625
Self-administered, mail, telephone and e-mail surveys	89,750	1	.250	22,438
Total	90,000	.....	.....	23,063

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: June 30, 2010.

Dennis O. Romero,

Deputy Director, Office of Program Services.

[FR Doc. 2010–16743 Filed 7–8–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day 10–0214]

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 project or to obtain a copy of data collection plans and instruments, call the CDC Reports Clearance Officer on 404–639–5960 or send comments to CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS D–74, 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 the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.