SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 2009 (74 FR 55557), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0658. The approval expires on March 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: April 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7948 Filed 4–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0174]

Agency Information Collection Activities; Proposed Collection; 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 Valid or Will Not Be Infringed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit written or electronic comments on the collection of information by June 7, 2010.

ADDRESSES: 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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, e-mail: *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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 (21 U.S.C. 355(c)(2)) 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 application 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) (21 CFR 314.50(h)) and 314.53 (21 CFR 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.

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	No. of Responses per Respondent	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 Reporting Burden Hours:					14,120

[1] There are no operating and maintenance costs or capital 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% 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 Sec. 314.50(h) (citing Sec. 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: April 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7891 Filed 4–7–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Interstate Administrative Subpoena.

OMB No.: 0970–0152.

Description: Section 452(a)(11) of the Social Security Act requires the Secretary of the Department of Health