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]

BILLING CODE 4160–01–S

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

and Human Services to promulgate a form for administrative subpoenas to be used in State child support enforcement programs to collect information for use in the establishment, modification and enforcement of child support orders in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the federal form for issuance of administrative subpoenas in interstate child support cases. Tribal IV–D agencies are not required to use this form but may choose to do so. OMB approval of this form is expiring in February 2011 and the Administration for Children and Families is requesting an extension of this form.

Respondents: State, local or Tribal agencies administering a child support enforcement program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Administrative Subpoena	35,286	1	0.50	17,643
Estimated Total Annual Burden Hours				17,643

In compliance with the requirements of section 506(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: April 5, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–7984 Filed 4–7–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Notice of Interstate Lien.

OMB No.: 0970–0153.

Description: Section 452(a)(11) of the Social Security Act requires the Secretary of Health and Human Services to promulgate a form for imposition of liens to be used by the State child support enforcement (Title IV–D) agencies in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the Federal form for imposition of liens in interstate child support cases. Tribal IV–D agencies are not required to use this form but may choose to do so. OMB approval of this form is expiring in February 2011 and the Administration for Children and Families is requesting an extension of this form.

Respondents: State, local or Tribal agencies administering a child support enforcement program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Notice of Lien	1,832,384	1	0.25	458,096

Estimated Total Annual Burden Hours: 458,096.

In compliance with the requirements of section 506(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)