

information they conduct or sponsor. The term “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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### Information Collection

#### 1. Type of Information Collection

**Request:** Revision of a currently approved collection; **Title of Information Collection:** Disclosure of State Rating Requirements; **Use:** The final rule “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” implements sections 2701, 2702, and 2703 of the Public Health Service Act (PHS Act), as added and amended by the Affordable Care Act, and sections 1302(e) and 1312(c) of the Affordable Care Act. The rule directs that states submit to CMS certain information about state rating and risk pooling requirements for their individual, small group, and large group markets, as applicable. Specifically, states will inform CMS of age rating ratios that are narrower than 3:1 for adults; tobacco use rating ratios that are narrower than 1.5:1; a state-established uniform age curve; geographic rating areas; whether premiums in the small and large group market are required to be based on average enrollee amounts (also known as composite premiums); and, in states that do not permit any rating variation based on age or tobacco use, uniform family tier structures and corresponding multipliers. In addition, states that elect to merge their individual and small group market risk pools into a combined pool will notify CMS of such election. This information will allow CMS to determine whether state-specific rules apply or Federal default rules apply. It will also support the accuracy of the federal risk adjustment methodology. **Form Number:** CMS-10454 (OMB Control Number 0938-1258); **Frequency:** On Occasion; **Affected Public:** State, Local, or Tribal Governments, Private Sector; **Number of Respondents:** 47; **Number of Responses:** 47; **Total Annual Hours:** 2,239. (For policy questions regarding this collection, contact Russell Tipps at 301-492-4371.)

#### 2. Type of Information Collection

**Request:** Revision of a currently approved information collection request; **Title of Information Collection:** Information Collection for Machine Readable Data for Provider Network and Prescription Formulary Content for FFM QHPs; **Use:** Under 45 CFR 156.122(d)(1)(2) and 156.230(c) and in the final rule, *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018* (CMS-9934-F), standards for qualified health plan (QHP) issuers are established for the submission of provider and formulary data in a machine-readable format to the Department of Health and Human Services (HHS) and for posting on issuer Web sites. These standards provide greater transparency for consumers, including by allowing software developers to access formulary and provider data to create innovative and informative tools. **Form Number:** CMS-10558 (OMB Control Number 0938-1284); **Frequency:** Annually; **Affected Public:** Private Sector, State, Business, and Not-for Profits; **Number of Respondents:** 397; **Number of Responses:** 397; **Total Hours:** 208. (For questions regarding this collection contact Joshua Annas at (301) 492-4407.)

#### 3. Type of Information Collection

**Request:** New collection of information request; **Title of Information Collection:** State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities; **Use:** The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), also called Marketplaces, including the Small Business Health Options Program (SHOP). The Exchanges, which became operational on January 1, 2014, enhance competition in the health insurance market, expand access to affordable health insurance for millions of Americans, and provide consumers with a place to easily compare and shop for health insurance coverage.

This Information Collection Request (ICR) serves as the formal request for a new data collection clearance associated with the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule (2018 Payment Notice). This ICR includes data collections related to the

ability of states to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in Qualified Health Plans in the Federally Facilitated Exchange (§ 155.220) and ICRs related to non-exchange entities (§ 155.260). **Form Number:** CMS-10650 (OMB Control Number 0939-NEW); **Frequency:** Annually; **Affected Public:** Private Sector, State, Business, and Not-for Profits; **Number of Respondents:** 107,207; **Number of Responses:** 107,207; **Total Annual Hours:** 512,141. (For questions regarding this collection contact Joshua Annas at (301-492-4407).

Dated: May 23, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017-10944 Filed 5-25-17; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0523]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 requirements governing applications for FDA approval to market a new drug.

**DATES:** Submit either electronic or written comments on the collection of information by June 26, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 25, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time

at the end of July 25, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2013-N-0523 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for FDA Approval to Market a New Drug." Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

#### **Application for FDA Approval To Market a New Drug**

*OMB Control Number 0910-0001—Extension*

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. The Agency has codified regulations regarding applications for FDA approval to market a new drug under 21 CFR part 314. This collection of information supports the regulatory requirements found in those regulations. The collection of information is necessary for FDA to make a scientific and technical determination whether the product is safe and effective for use, and is summarized as follows:

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes information about the applicant, the submission, and a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival

copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: (1) Chemistry, manufacturing, and controls; (2) nonclinical pharmacology and toxicology; (3) human pharmacokinetics and bioavailability; (4) microbiology; (5) clinical data; (6) statistical; and (7) pediatric use sections.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application. However, burden hours for § 314.50(h) are approved under OMB control numbers 0910–0513, Patent Certification Forms 3542 and 3542a and 0910–0786, Abbreviated New Drug Applications and 505(b)(2) Applications and are therefore not included among the estimates found in table 1.

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug substance, drug product, or method of use. Sections 314.50(i)(1)(i)(C) and 314.54(i) and (j) require that patent certification information be submitted for each patent listed in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (the Orange Book) for a drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product in the original 505(b)(2) application and was submitted and was approved before the original 505(b)(2) application was submitted. Burden for these provisions is included under OMB control number 0910–0786.

Section 314.50(j) requires that applicants who request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that the application contain a financial certification or disclosure statement or both.

Section 314.50(l) requires that an archival, review, and field copy of the application be submitted, including the

content of labeling and all labeling and labels.

Section 314.52 requires that any notice of certification of invalidity, unenforceability, or non-infringement of a patent to each patent owner and the NDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend its application at the time notice is provided to include a statement certifying that the required notice has been provided. A 505(b)(2) applicant also is required to amend its application to document receipt of the required notice. Burden hours for these provisions are included in OMB control number 0910–0786.

Section 314.53 sets forth the patent information requirements for applicants who submit applications or amendments to the application filed under section 505(b)(2) of the FD&C Act or supplements to the approved 505(b)(2) application. Burden hours for these collections are approved in OMB control number 0910–0786.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the FD&C Act. The burden estimate for 505(b)(2) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (l).

Section 314.55 sets forth the assessment requirements for each application. The burden estimate for 505(b)(2) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (l).

Section 314.60 sets forth reporting requirements and patent certification requirements for sponsors who amend an unapproved 505(b)(2) application. Burden hours for the § 314.60(f) collections are approved under OMB control number 0910–0786.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A).

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. The burden hours for § 314.80(i) are approved under OMB

control numbers 0910–0230, Adverse Drug Experience Reporting and 0910–0291, MedWatch: FDA’s Medical Reporting Program and therefore burden estimates are not included in table 1.

Section 314.81(b)(1) requires that NDA and ANDA field alert reports be submitted to FDA (Forms FDA 3331 and 3331a).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253).

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. The burden hours for § 314.81(b)(3)(iii) are approved under OMB control number 0910–0045, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution and therefore are not included in table 1.

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. The information collection burden estimate for NDA waiver requests is included in table 1 under the estimates for each section that is in part 314, subpart B.

Section 314.93 sets forth requirements for submitting a suitability petition to request a change from a listed drug in accordance with §§ 10.20 and 10.30. The burden hours for § 314.93 are approved under OMB control number 0910–0191, Administrative Practices and Procedures; Formal Evidentiary Public Hearing and are not included in table 1.

Section 314.94(a) through (d) require that an ANDA contain the following information: (1) Application form; (2) table of contents; (3) basis for ANDA submission; (4) conditions of use; (5) active ingredients; (6) route of administration, dosage form, and strength; (7) bioequivalence; (8) labeling; (9) chemistry, manufacturing, and controls; (10) samples; and (11) patent certification.

Section 314.95 requires that any notice of certification of invalidity or non-infringement of a patent to each patent owner and the NDA holder be sent by ANDA applicants.

Section 314.96 sets forth requirements for amendments to an unapproved ANDA.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for certain changes to the application. Approval of burden hours for information collections for

§§ 314.95, through 314.97 are covered under OMB control number 0910–0786.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements for ANDAs. The burden hours for § 314.98(a) are approved under OMB control numbers 0910–0230 and 0910–0291 and are not included in table 1.

Section 314.98(b) requires other postmarketing reports for ANDAs: (1) Field alert reports (Form FDA 3331a); (2) annual reports (Form FDA 2252); and (3) advertisements and promotional labeling (Form FDA 2253). (The information collection burden estimate for field alert reports is included in table 1 under § 314.81(b)(1); the estimate for annual reports is included under § 314.81(b)(2); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection burden estimate for ANDA waiver requests is included in table 1 under the estimates for each section that is in part 314, subpart C.)

Section 314.101(a) states that if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c) requires notice to FDA by the first applicant to submit a substantially complete ANDA containing a certification that a relevant patent is invalid, unenforceable, or will not be infringed of the date of first commercial marketing. The burden estimate for § 314.107(c) is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (j).

Section 314.107(e) requires that an applicant submit a copy of the entry of the order or judgment to FDA within 10 working days of a final judgment. The burden estimate for § 314.107(e) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (j) and is approved under OMB control number 0910–0786.

Section 314.107(f) requires that ANDA or section 505(b)(2) applicants notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner must also notify FDA of the filing of any legal action for patent

infringement. If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within the 45-day period, the patent owner or approved application holder may submit to FDA a waiver in the specified format. The burden estimate for § 314.107(f) is included in table 1 under the estimates for § 314.50 (a) through (g) and (i) through (j) and is approved under OMB control number 0910–0786.

Section 314.110(b)(3) states that, after receipt of an FDA complete response letter, an applicant must either: (1) Resubmit the application addressing all the deficiencies identified in the complete response letter; (2) withdraw the application or; (3) request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. The burden hours for § 314.110(b)(3) are included under parts 10 through 16 (21 CFR parts 10 through 16, OMB control number 0910–0191) hearing regulations, in accordance with § 314.201, and are not included in table 1.

Section 314.122(a) requires that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. The burden hours for § 314.122(a) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. The burden hours for § 314.122(d) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Sections 314.125 and 314.127 state that FDA may refuse to approve an NDA or an ANDA and will provide the applicant written notice of an opportunity for a hearing under § 314.200 along with the reason for refusal to approve the application, including lack of a patent certification or statement with respect to each listed patent for an approved drug product that is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted and was approved before the original 505(b)(2) was submitted. The burden hours for §§ 314.125 and 314.127 (refuse to approve an ANDA) are included under parts 10 through 16 hearing regulations (in accordance with § 314.201) and approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. The burden hours for § 314.126(c) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Sections 314.150(a) and (b) and 314.151(a) and (b) set forth requirements for the withdrawal of approval of an NDA or ANDA and the applicant's opportunity for a hearing and submission of comments. The burden hours for § 314.151(a) and (b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. The burden hours for § 314.151(c) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.153(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. The burden hours for § 314.153(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.161(b) and (e) sets forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. The burden hours for § 314.161(b) and (e) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. The burden hours for § 314.200(c), (d), and (e) are included under parts 10 through 16 hearing regulations, in accordance with

§ 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.200(f) states that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. The burden hours for § 314.200(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.200(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. The burden hours for § 314.200(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that

extraordinary circumstances exist. The burden hours for § 314.430 are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.530(c) and (e) states that if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. The burden hours for § 314.530(c) and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. The burden hours for § 314.530(f) are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.550 requires an applicant with a new drug product being considered for accelerated approval to submit copies of all promotional materials to the FDA during the preapproval and post-approval periods.

Section 314.610(b)(1) requires that applicants include a plan or approach to postmarketing study commitments in

applications for approval of new drugs when human efficacy studies are not ethical or feasible, and provide status reports of postmarketing study commitments. The burden estimate for § 314.610(b)(1) is included in table 1 under the estimates for §§ 314.50 (a) through (f), (k), and (l) and 314.81(b)(2)).

Section 314.610(b)(3) requires that applicants propose labeling to be provided to patient recipients in applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden estimate for § 314.610(b)(3) is included in table 1 under the estimates for § 314.50(e).

Section 314.630 requires that applicants provide postmarketing safety reporting for applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden hours for § 314.630 are approved under OMB control numbers 0910–0230 and 0910–0291 and therefore not included in table 1.

Section 314.640 requires that applicants provide promotional materials for applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden estimate for § 314.640 is included in table 1 under the estimates for § 314.81(b)(3)(i)).

Accordingly, we estimate the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section/ [FDA Form No.]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.50(a)–(g), (i)–(l) [356h]—Content and format of a 505(b)(1) or 505(b)(2) application .....	378	1.33	503	1,921	966,263
314.52—Non-infringement of patents (NDAs) .....	7	3	21	16	336
314.95—Non-infringement of patents (ANDAs) .....	209	3	627	16	10,032
314.60—Amendments .....	564	9.96	5,618	80	449,440
314.65—Withdrawal of unapproved applications .....	27	71.63	1,934	2	3,868
314.70 and 314.71—Supplements and submissions .....	838	7.04	5,897	150	884,550
314.72—Change of ownership .....	142	2.04	289	2	578
314.81—Other postmarketing reports and 314.81(b)(1) [3331 and 3331a] field alert reports .....	342	19.98	6,834	8	54,672
314.81(b)(2) [2252]—Annual reports .....	913	5.07	4,632	40	185,280
314.81(b)(3)(i) [2253]—Promotional labeling .....	529	81.66	43,198	2	86,396
314.94(a) and (d)—ANDA content .....	180.5	3.75	676.5	480	324,720
314.96(a)(1)—Amendments to unapproved ANDAs .....	514	26.66	13,647	80	1,091,760
314.97—Supplements to ANDAs .....	343	17.57	6,027	80	482,160
314.99(a)—Responsibilities of ANDA Applicants .....	265	7.04	1,867	2	3,734
314.101(a)—ANDA filing .....	1	1	1	.5	.5
314.420—Drug Master Files .....	500	2.06	1,028	(30 minutes) 61	62,708
314.550—Promotional material and subpart H applications .....	29	7.76	225	120	27,000
<b>Total .....</b>					<b>4,633,497.5</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 22, 2017.  
**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*  
 [FR Doc. 2017-10818 Filed 5-25-17; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-0084]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)**

**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 June 26, 2017.

**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 emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0471. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)); OMB Control Number 0910-0471—Extension**

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) authorizes FDA to require: (1) Manufacturers to report medical device-related deaths, serious injuries, and malfunctions and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a “. . . subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data

on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910-0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions, which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and includes approximately 250 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same Web site as the report information.

The burden estimate is based on the number of facilities participating in MedSun (250). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

In the **Federal Register** of January 19, 2017 (82 FR 6566), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adverse event reporting .....	250	15	3,750	.75 (45 minutes).	2,813

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 22, 2017.  
**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*  
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