Regional Field Office, China Office
Regional Field Office, Europe Office
Regional Field Office, India Office
Regional Field Office, Latin America Office
Office of Trade, Mutual Recognition and International Arrangements
Office of Legislation
Office of Policy
Policy Engagement and Coordination Staff
Regulations Editorial Staff
Regulations Policy and Management Staff

DCP. ORGANIZATION. The Office of the Chief Scientist is headed by the Chief Scientist and includes the following organizational units:

OFFICE OF THE CHIEF SCIENTIST
Advisory Committee Oversight and Management Staff
Office of Counter-Terrorism and Emerging Threats
Office of Laboratory Safety
Office of Regulatory Science and Innovation
Office of Scientific Integrity
Office of Scientific Professional Development
National Center for Toxicological Research

DCQ. ORGANIZATION. The Office of Women's Health is headed by the Assistant Commissioner for Women's Health and includes the following organizational units:

OFFICE OF WOMEN'S HEALTH

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide. Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Alex M. Azar, II,

Secretary, HHS.

[FR Doc. 2019–10431 Filed 5–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0662]

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

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 reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment or a supplement to an NDA.

DATES: Submit either electronic or written comments on the collection of information by July 19, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 19, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 19, 2019. 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.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–0662 for ''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.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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 Dockets Management Staff, 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, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Applications for Food and Drug Administration Approval To Market a New Drug: Patent Submission and Listing Requirements

OMB Control Number 0910–0513—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C 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 that claims the drug for which the applicant submitted the application or that 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 FD&C 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. After approval of an NDA, under section 505(b)(1) of the FD&C Act, FDA publishes the patent information in the list entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book). When the patent information is submitted after NDA approval, section 505(c)(2) of the FD&C Act directs FDA to publish the patent information upon its submission.

FDA regulations in §§ 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 to an NDA, and also require persons submitting an NDA, an amendment, or a supplement to make a detailed patent declaration on Form FDA 3542a, or when submitting information on a patent after approval of the NDA or supplement, to make a detailed patent declaration using Form FDA 3542.

The reporting burden for submitting an NDA, an amendment, or a supplement to an NDA in accordance with § 314.50(a) through (f), (i), (h), and (k) has been estimated by FDA and the collection of information has been approved by OMB under control number 0910–0001. In addition, the reporting burden for submitting an appropriate patent certification or statement for each patent listed in the Orange Book for one drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product for which the original 505(b)(2) application was submitted (if certain criteria are met) in accordance with § 314.50(i)(1)(i)(C) and the reporting burden for submitting an amended patent certification in certain circumstances in accordance with § 314.50(i)(6) are approved by OMB under OMB control number 0910–0786. In addition, the reporting burden for responding to a patent listing dispute in accordance with § 314.53(f)(1) and the reporting burden for submitting corrections, changes, or withdrawal of patent information in accordance with § 314.53(f)(2) also are approved by OMB under OMB control number 0910–0786. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as described below, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, or an amendment or a supplement to an NDA, contain patent information described under § 314.53. Section 314.53 requires that an applicant submitting an NDA, or an amendment or a supplement to an NDA, except as provided in § 314.53(d)(2), submit on Forms FDA 3542 and 3542a the required patent information described in this section. Section 314.53(d)(2) requires submission of patent information only for a supplement that seeks approval to add or change the dosage form or route of administration, to add or change the strength, to change the drug product from prescription to over-the-counter use, or to revise previously submitted patent information that differently or no longer claims the product as changed by the supplement.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, or an amendment or a supplement to an NDA (collectively referred to as an ''application''), the required patent declaration(s) on Form FDA 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(s) 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 FDA 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 FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method(s) of use of the product for listing in the Orange Book. For patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent. In addition, an NDA applicant's amendment to the description of the approved method(s) of use claimed by the patent must be submitted within the timeframes described in §§ 314.50(i)(4) and 314.94(a)(12)(vi) (21 CFR 314.94(a)(12)(vi)) to be considered timely filed.

Description of Respondents: The respondents to this collection of information are NDA applicants for original applications, amendments, or supplements to an NDA or NDA applicants submitting information on a patent after approval of the NDA or supplement.

The final rule ''Abbreviated New Drug Applications and 505(b)(2) Applications,'' implemented portions of Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and also amended certain regulations regarding 505(b)(2) applications and abbreviated new drug applications (ANDAs) to facilitate compliance with and efficient enforcement of the FD&C Act (81 FR 69580; October 6, 2016) (MMA Final Rule). In the MMA Final Rule, we estimated that the burden for Form FDA 3542a would be reduced by 5 hours from 20 hours to 15 hours per response; we further estimated that the burden for Form FDA 3542 would increase by 5 hours from 5 to 10 hours per response. The burden hours were adjusted to shift a portion of the time spent preparing Form FDA 3542a to the estimated time spent preparing Form FDA 3542 to reflect the additional time spent by the NDA holder to develop the use code in accordance with FDA's revised regulations and identify the specific section(s) and subsection(s) of labeling that describe the specific approved method of use claimed by the patent. The burden hours of Forms FDA 3542 and 3542a in this notice reflect the reporting burden approved by OMB under OMB control number 0910–0786 in connection with the MMA Final Rule. The effective date of the MMA Final Rule was December 5, 2016. Consequently, the annual reporting burden estimated below is based on calendar year 2017 data only to reflect the post-MMA Final Rule regulatory requirements and reporting burden estimate.

FDA requests OMB approval for the following information collection:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses CY 2017	Hours per response	Total hours
Form FDA 3542	281	2.875	808	10	8,080
Form FDA 3542a	310	2.084	646	15	9,690
Total	.....	.....	.....	.....	17,770

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

For purposes of this analysis, we consider the number of respondents to correspond to the number of NDAs and efficacy supplements submitted or approved, respectively, in calendar year (CY) 2017, even though one company may submit or hold multiple NDAs or may submit multiple efficacy supplements to one or more NDAs. FDA approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds to 281 respondents. Based on information provided by the Orange Book staff, approximately 623 patent records were created in CY 2017, which corresponds to an estimated 513 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for NDAs approved in CY 2017 and an estimated 110 Forms FDA 3542 submitted to FDA for listing of patent information in the Orange Book for efficacy supplements approved in CY 2017. In addition, based on information provided by the Orange Book staff and FDA's experience, we estimate that approximately 185 Forms FDA 3542 were submitted in CY 2017 to modify patent information, which results in an estimated total of 808 Forms FDA 3542 submitted in CY 2017.

During calendar year 2017, FDA received 141 original NDAs and 169 efficacy supplements to NDAs for FDA review and approval. We estimate that applicants submitted approximately 405 Forms FDA 3542a for the original NDAs submitted during CY 2017. In addition, based on a review of the submitted efficacy supplements, FDA received 241 Forms FDA 3542a with the efficacy supplements received during CY 2017, resulting in a total of 646 Forms FDA 3542a submitted in CY 2017.

Our estimated burden for the information collection reflects an overall decrease. We attribute this adjustment to a decrease in the number of duplicative submissions of Forms FDA 3542a and 3542 in connection with supplements submitted or approved after the effective date of the MMA final rule, and improved data collection from upgraded data software tools.

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10421 Filed 5–17–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.