

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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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

<sup>1</sup> 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.