



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 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 either electronic or written comments on the collection of information by (INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER.)

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-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 and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [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 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 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 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 FD&C 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 § 505(b)(1) of the FD&C 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, § 505(c)(2) of the FD&C 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 below, 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 requests OMB approval for the following information collection:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section § 314.50 (citing § 314.53)	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	241	3.4	819	20	16,380
Form FDA 3542	200	3.4	680	5	3,400
Total					19,780

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

The numbers of patents submitted to FDA for listing in the Orange Book in 2012, 2013, and 2014 were 458, 509, and 617, respectively, for an annual average of 528 (458 patents + 509 patents + 617 patents)/3 years = 528 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 74 (528 patents × 14 percent) patents will be multiple listings, and there will be a total of 602 patents (528 patents + 74 patents = 602 patents) declared

on Form FDA 3542. We approved 86, 94, and 107 NDAs in calendar years 2012, 2013, and 2014, respectively, of which we estimate based on our previous review that approximately 71 percent submitted patent information for listing in the Orange Book. The remaining NDAs submitted Form FDA 3542 as required and declared that there were no relevant patents. We also approved approximately 101, 101, and 110 NDA supplements in FYs 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 200 instances (based on an average of 96 NDA approvals and 104 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 3.4 declarations (602 patent declarations + 74 no relevant patent declarations)/200 instances = 3.4 declarations per instance) on Form FDA 3542. We filed 112, 116, and 113 NDAs in 2012, 2013, and 2014, respectively, and 112, 112, 156 NDA supplements in 2012, 2013, and 2014, respectively, for which submission of a patent declaration would be required. We estimate there will be 241 instances (based on an average of 114 NDAs filed and 127 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 819 declarations (241 instances  $\times$  3.4 declarations per instance = 819 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 § 314.50(h) (citing § 314.53) and Forms FDA 3542 and 3542a will be approximately 5 hours and 20 hours per response, respectively.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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