UNITED STATES FOOD & DRUG ADMINISTRATION

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

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations and associated forms. 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 new drug application (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 section 505(b)(1) of the FD&C Act, we publish patent information after approval of an NDA in the list entitled "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (the Orange Book). If patent information is submitted after NDA approval, section 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 to make a detailed patent declaration. To assist respondents in this regard, we have developed the following forms:

- Form FDA 3542 – *Patent Information Submitted Upon and After Approval of an NDA or Supplement*; and

- Form FDA 3542a - *Patent Information Submitted With the Filing of an NDA, Amendment, or Supplement*.

As set forth in the regulations, patent information must be submitted on Form FDA 3542 within 30 days following approval of an NDA or supplemental application. For patents issued after approval of the NDA or supplement, the NDA holder must submit the required patent information within 30 days of the issuance of the patent for it to be considered timely filed. If

the NDA holder timely submits the required patent information, but FDA notifies the NDA holder that its Form FDA 3542 is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of FDA's notification to be considered timely filed as of the date of the original submission of patent information. New patent information may still be submitted after 30 days of the issuance of the patent, but such information is not considered timely filed.

We therefore request OMB approval of the information collection provisions in the applicable regulations and associated forms, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection is required by statute and agency regulations as part of the NDA or, in the case of subsequently issued patents, as amendments to the unapproved NDA. When the NDA is approved, we collect this information in a separate submission that lists the patents that claim the drug substance or drug product described in the approved NDA or supplement or that claim an approved method of using the drug. As discussed above, we use the patent information provided in Form 3542 to list patents in the Orange Book. Federal law specifically requires us to publish such patent information. ANDA and 505(b)(2) applicants that rely upon FDA's finding of safety and/or effectiveness for a listed drug are required to submit an appropriate patent certification or statement for each patent listed in the Orange Book.

3. Use of Improved Information Technology and Burden Reduction

Forms FDA 3542 and FDA 3542a may be filled-out electronically and submitted to FDA.

4. Efforts to Identify Duplication and Use of Similar Information

Information collection associated with applications to market a new drug provided for in 21 CFR part 314 are approved under OMB Control No. 0910-0001. This information collection accounts for burden specifically ascribed to Forms FDA 3542 and 3542a, instruments used for collecting patent information for publication in the Orange Book. We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue impact on small entities. At the same time, we provide resources to small business through contacts within the agency including the Center for Drug Evaluation and Research (CDER), and through the Division of Manufacturers Assistance and Training component in the Center for Biologics Evaluation and Research (CBER). We also provide small business compliance guidances on our website at: https://search.usa.gov/search?query=small+business+compliance+guide&affiliate=fda1.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is determined by respondents and consistent with statutory requirements.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60 day notice inviting public comment in the Federal Register of May 20, 2019. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted is protected under 21 CFR 314.430 and 21 CFR part 20. To address this element of the supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. Information collected does include personally identifiable information (PII) and other data of a personal nature: patent information (including patent numbers and expiration dates); name; address; country; fax number; telephone number; and email address. We have determined, however, that the collection is not subject to the Privacy Act of 1974 and therefore notice and other requirements of the Privacy Act do not apply. Specifically, we do not use the name or any other personal identifier to routinely retrieve records from the information collected. Also, we have minimized the PII to be collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

The information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate –

We estimate the burden of the information collection as follows:

Table 1. – Estimated Annual Reporting Burden[1]

Patent declaration as prescribed by 21 CFR parts 314.50 and 314.53	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	310	2.084	646	15	9,690
Form FDA 3542	281	2.875	808	10	8,080
TOTAL	591		1454		17,770

1. There are no capital, or operating and maintenance costs associated with the information collection.

For 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. During calendar year 2017, we received 141 original NDAs and 169 efficacy supplements for review and approval from 310 respondents, for a total of 646 Form FDA 3542a submissions during CY 2017. This is reflected in row 1. Similarly, we approved 127 NDAs and 154 efficacy supplements to NDAs during CY 2017, which corresponds with 281 respondents. Based on our records, a total of 808 Form FDA 3542 submissions we received during CY 2017, as reflected in row 2.

12b. Annualized Cost Burden Estimates –

Based on the hours estimated above, the burden hour costs for the reporting requirements would be as follows:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
NDA applicants	17,770	$88	$1,563,760

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no capital costs or operating and maintenance costs (or start-up costs or service costs) projected as a result of the information collection.

14. Annualized Cost to the Federal Government

Costs to operate the information collection are absorbed through agency resources allocated in support of our new drug application program.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustment. Based on fewer submissions we have decreased our cumulative estimate by 45 annual hours and 2,010 responses. At the same time, we have uploaded previously reported costs at question 12b to be reflected at www.reginfo.gov.

16. Plans for Tabulation and Publication and Project Time Schedule

As described above, we use the information collected to publish patent lists in the Orange Book.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate and is included on the applicable forms.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.