OMB INFORMATION COLLECTION
OMB Control Number 0910-0513
Supporting Statement

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

A. Justification

1. Circumstances Necessitating Information Collection

FDA is requesting that OMB revise and extend approval under the PRA for the information collection contained in the final rule entitled "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" (68 FR 36676, June 18, 2003) (the June 2003 final rule).

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 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 act, we publish patent information after approval of a NDA application 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 act directs us to publish the information upon its submission.

The June 2003 final rule clarified the types of patent information that must and must not be submitted to FDA as part of a NDA, an amendment, or a supplement. The June 2003 final rule also required persons submitting a NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using required forms (Form FDA 3542a and Form FDA 3542).

Certain sections of the June 2003 final rule regarding the application of 30-month stays on approval of certain abbreviated new drug applications (ANDAs) and certain other new drug applications, known as 505(b)(2) applications, submitted under the act, were superseded by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, signed December 8, 2003. The affected sections of the regulations issued in the June 2003 final rule — §§ 314.52(a)(3) and 314.95(a)(3) (21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3)) — were revoked by the technical amendment to the June 2003 final rule published in the Federal Register of March 10, 2004 (69 FR 11309). Accordingly, FDA's request to extend approval under the PRA for the collection of information contained in the June 2003 final rule is revised to exclude the revoked sections of the regulations, §§ 314.52(a)(3) and 314.95(a)(3), and certain sections of the regulations, §§ 314.50(i)(1)(i) and 314.94(a)(12), which were included in the estimated annual reporting burden to describe an information collection burden associated with the revoked sections of the regulations.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that a NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting a NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on Form 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 a 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 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.

2. How, by Whom, and for What Purpose Information Used

We collect this information as part of the NDA or, in the case of later-obtained patents, as amendments to the NDA. When the NDA is approved, we collect this information in a separate submission that reflects the patents that cover the drug as we have approved it, including the specific methods of use of the drug for which we granted approval.

We use the patent information in the reports to list patents in our approved drug products list titled, "Approved Drug Products With Therapeutic Equivalence Evaluations." Federal law specifically requires us to publish such patent information. ANDA and 505(b)(2) application applicants can then consult the listed patent information to prepare their patent certification statements or to identify patents that claim a specific drug substance, drug product, or method of use for that product.

3. Consideration of Information Technology

The regulations do not specifically prescribe the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Respondents are free to use whatever forms of information technology that may best assist them in complying with the rule.

4. Efforts to Identify Duplication and Similar Information Already Available

The information that is collected is not already available to FDA. Such information is

available only from NDA applicants and NDA holders, and will vary for each drug. Because our patent listing function is ministerial, only the NDA applicant or NDA holder has the ability to identify the patents for which relevant information is to be submitted.

FDA is the only agency that reviews and approves NDAs, 505(b)(2) applications, and ANDAs. We thus have not undertaken literature searches or contacted staff of other organizations with respect to this information collection. Section 505(b)(1) of the act requires NDA applicants to provide patent information as part of the NDA. Sections 505(b) and 505(j) of the act require certain 505(b)(2) application applicants and ANDA applicants to provide a notice of certification of invalidity or noninfringement of patent to patent owners and NDA holders in certain situations; this notification is part of the application process. Therefore, no duplication of data exists.

The importance of obtaining such data relates to adherence to the law and regulatory requirements for patent submissions, and ensuring that ANDA and 505(b)(2) applicants adhere to the appropriate legal and regulatory requirements for certifying to those patents. Adherence to those requirements, in turn, governs whether and when we can approve such ANDA and 505(b)(2) applications.

5. Small Business

This information collection does not have a significant impact on small businesses.

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

Failure to collect the information could result in incomplete, erroneous, or misleading patent information being listed by FDA and prompt 505(b)(2) application applicants and ANDA applicants to make incorrect patent certifications, thereby exposing those applicants to potential litigation for patent infringement. Ultimately, the failure to collect the information could have an adverse effect on the protection of patented drug products and on the availability of generic drug products.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The reporting requirements are consistent with the guidelines in 5 CFR 1320.5(d)(2). The regulations do not require reporting to occur more frequently than the quarterly basis described in §320.5(d)(2)(i), nor does it require multiple copies of the reports.

We do not require respondents to keep records more than 3 years. No statistical data is used. The collection does not include a pledge of confidentiality. Respondents are not required to submit trade secrets, proprietary, or other confidential information.

8. Consultation Outside the Agency

The agency relied on information provided by regulated entities and its own expertise to estimate the amount of time and cost needed to prepare the reports described in the rule. As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided opportunity for public comment on the information collection requirements of the proposed rule that published in

the Federal Register on October 24, 2002 (67 FR 65448). The proposed rule received over 35 comments to which FDA responded in the preamble of the final rule (June 18, 2003; 68 FR 36676).

In addition, in the Federal Register of June 2, 2006 (71 FR 32099), FDA requested comments on the information collection. One comment was received . . . . . .

9. Payment or Gift to Respondents

FDA did not provide any payment or gifts to respondents.

10. Confidentiality of Information

Assurances of confidentiality (beyond those already existing in federal law and FDA regulations) are unnecessary.

11. Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Burden Hours and Explanation

Following publication of the June 2003 final rule, the numbers of patents submitted to us for listing in the Orange Book in 2004 and 2005 were 244 and 295, respectively, for an annual average of 269.5 ((244 patents + 295 patents) / 2 years = 269.5 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 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 38 (269.5 patents x 14 percent) patent declarations will be multiple listings, and there will be 308 (269.5 declarations + 38 declarations = 307.5 declarations) total annual patent declarations on Form 3542.

As we approved 113 and 78 NDAs in 2004 and 2005, respectively, we assume there will be 96 ((113 approvals + 78 approvals) / 2 years = 95.5 approvals / year) instances where a NDA holder would be affected by the patent declaration requirements, and that each of these NDA holders would, on average, submit 3.2 (308 declarations / 96 instances = 3.2 declarations per instance) declarations on Form 3542.

As we received 112 and 115 NDAs in 2004 and 2005, respectively, we assume there will be 114 ((112 applications + 115 applications) / 2 years = 113.5 applications / year) instances where a 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 365 (114 instances x 3.2 declarations per instance = 365 declarations) declarations on Form 3542a submitted with these applications.

The previous burden hour estimate of 1,684 hours for § 314.50 covered paragraphs (a) through (f), and (k) in addition to paragraph (h) (citing § 314.53) and Forms 3542 and 3542a (see June 2003 final rule), due to the difficulty in determining what proportion of the burden hour estimate for §§ 314.50(a) through (f), (h), and (k), were attributable to patent declarations. Based upon information provided by regulated entities and other information, we estimate that the information collection burden associated with § 314.50(h) (citing § 314.53) and Forms 3542a and 3542 will be

approximately 20 hours and 5 hours per response, respectively.

Thus, the information collection burden for § 314.50(h) (citing § 314.53) and Forms 3542 and 3542a will decrease from the estimate we made in the June 2003 final rule for §§ 314.50(a) through (f), (h), and (k), and Forms 3542 and 3542a of 498,464 hours to 8,840 hours ((365 annual responses x 20 hours per response = 7,300 hours) + (308 annual responses x 5 hours per response = 1,540 hours) = 8,840 total hours).

FDA requests OMB approval for the following information collection:

Table 1. – Estimated Annual Reporting Burden

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	114	3.2	365	20	7,300
Form FDA 3542	96	3.2	308	5	1,540
Total Reporting Burden Hours:					8,840

Note: There are no operating and maintenance costs or capital costs associated with this collection of information.

13. Annual Cost to Respondents

FDA estimates an hourly wage of $65 per hour (including overhead and expenses) for industry personnel to comply with the requirements of these regulations. Therefore, the total cost to industry would be $574,600 (8,840 x $65).

There are no total capital or start-up costs or service costs projected due to the minimal nature of the reporting requirements.

14. Annual Cost to the Government

We estimate the annualized cost to the federal government to be negligible. While we cannot predict whether the final rule would result in an increase, decrease, or no change in the volume of patent information submitted to FDA, our patent duties are solely ministerial and consist largely of listing patent information in "Approved Drug Products With Therapeutic Equivalence Evaluations."

The proposed change regarding the 30-month stay and its potential to reduce the number of notices going from ANDA and 505(b)(2) applicants to NDA holders and patent owners would have little or no direct impact on the federal government because we do not receive copies of these notices. We do receive documentation to show that the NDA holder and patent holder received notice from the ANDA or 505(b)(2) applicant, but this is a ministerial action and, other than filing the documentation as part of the ANDA or 505(b)(2) application, we take no action regarding such documentation. Furthermore, because we estimate that the number of notices would decrease by 37 (from 37 respondents filing two notices per year to 37 respondents filing only one notice per year), we believe the government's cost savings associated with 37 pieces of documentation are also negligible.

15. Changes from Previous Approval

The information collection burden for § 314.50(h) (citing § 314.53) and Forms 3542 and 3542a will decrease from the estimate we made in the June 2003 final rule for §§ 314.50(a) through (f), (h), and (k), and Forms 3542 and 3542a of 498,464 hours to 8,840 hours ((365 annual responses x 20 hours per response = 7,300 hours) + (308 annual responses x 5 hours per response = 1,540 hours) = 8,840 total hours).

As stated earlier, certain sections of the June 2003 final rule regarding the application of 30-month stays on approval of certain ANDAs and certain other new drug applications, known as 505(b)(2) applications, submitted under the act, were superseded by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, signed December 8, 2003. The affected sections of the regulations issued in the June 2003 final rule — §§ 314.52(a)(3) and 314.95(a)(3) (21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3)) — were revoked by the technical amendment to the June 2003 final rule published in the Federal Register of March 10, 2004 (69 FR 11309). Accordingly, FDA's request to extend approval under the PRA for the collection of information contained in the June 2003 final rule is revised to exclude the revoked sections of the regulations, §§ 314.52(a)(3) and 314.95(a)(3), and certain sections of the regulations, §§ 314.50(i)(1)(i) and 314.94(a)(12), which were included in the estimated annual reporting burden to describe an information collection burden associated with the revoked sections of the regulations.

16. Statistical Reporting

Information collected under this requirement will not be published.

17. Exemption for Display of Expiration Date

We do not seek an exemption from displaying the expiration date.

18. Exemption to Certification Statement

We are not requesting any exemption from the certification statement identified in Item 19 of form OMB Form 83-1.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request

FDA

2. OMB control number b. [x] None

a. 0910 - 0513

3. Type of information collection (*check one*)

a. [ ] New Collection

b. [x] Revision of a currently approved collection

c. [ ] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)

a. [x] Regular submission

b. [ ] Emergency - Approval requested by at close of comment period

c. [ ] Delegated

5. Small entities

Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date

a. [X] Three years from approval date b. [ ] Other Specify: ____/

7. Title 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

8. Agency form number(s) (*if applicable*)

9. Keywords Persons and businesses.

10. Abstract This action 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.

11. Affected public (*Mark primary with "P" and all others that apply with "x")*

a. ___ Individuals or households d. ___ Farms

b. _x_ Business or other for-profit e. ___ Federal Government

c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)

a. [ ] Voluntary- (guidance document)

b. [x] Required to obtain or retain benefits

c. [ ] Mandatory

13. Annual recordkeeping and reporting burden

a. Number of respondents 210 _____

b. Total annual responses 673 _____

1. Percentage of these responses collected electronically 0 %

c. Total annual hours requested 8,840 _____

d. Current OMB inventory 498,464 _____

e. Difference 489,624 _____

f. Explanation of difference

1. Program change _____

2. Adjustment Revocation of certain requirements.

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs 0

b. Total annual costs (O&M) 0

c. Total annualized cost requested 0

d. Current OMB inventory 0

e. Difference 0

f. Explanation of difference

1. Program change _____

2. Adjustment _____

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)

a. __ Application for benefits e.__ Program planning or management

b. __ Program evaluation f.__ Research

c. __ General purpose statistics g._x_ Regulatory or compliance

d. __ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*

a. [ ] Recordkeeping b. [ ] Third party disclosure

c. [x] Reporting

1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly

4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually

7. [ ] Biennially 8. [ ] Other (describe) _____

17. Statistical methods

Does this information collection employ statistical methods

[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)

	Name: Karen Nelson Phone: 827-1482