4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0662]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0513. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Food and Drug Administration, 8455 Colesville

Rd., COLE- 14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 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." Under section 505(b)(1), we publish the patent information after approval of the NDA in the list entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book). 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 that requires patent information be submitted after NDA approval when the NDA holder could not have submitted the patent information with its application. Under section 505(c)(2) of the FD&C Act, we publish the patent information upon its submission.

FDA regulations at § 314.50(h) and § 314.53 (21 CFR 314.50(h) and 314.53) implement these statutory requirements and 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. The regulations under

§ 314.53 direct sponsors of an NDA, an amendment, or a supplement, to make detailed patent declarations using Forms FDA 3542 and 3542a as appropriate. While the information collection burden for submitting other required elements of an NDA, an amendment, or supplement in accordance with § 314.50(a) through (f), and (k) is approved under OMB control number 0910-0001, this information collection identifies burden associated with patent submission and listing, as explained below.

Specifically, a patent declaration is required 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. 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 of use for listing in the Orange Book. In addition, 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. 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.

Description of Respondents: The respondents to this collection of information are sponsors of an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval.

In the Federal Register of February 2, 2016 (81 FR 5465), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received but was not responsive to the four collection of information topics solicited and is therefore not addressed.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR 314.50 and 314.53	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Burden per Response	Total Hours
Form FDA 3542; patent information submitted upon and after approval of an NDA or supplement	200	3.4	680	5	3,400
Form FDA 3542a; patent information submitted with the filing of an NDA, amendment, or supplement	241	3.4	819	20	16,380
TOTAL					19,780

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

The number 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 patents ([458 + 509 + 617]/3 years = 528). Because many of these individual patents are included in multiple NDA submissions, there may 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 74 patents (528 × 14 percent) will be multiple listings for a total of 602 patents (528 + 74 = 602) as declared on Form FDA 3542. We approved 86, 94, and 107 NDAs in calendar years 2012, 2013, and 2014, respectively, of which we estimate 71 percent submitted patent information for listing in the Orange Book. The remaining Form FDA 3542 submissions

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. Based on an average of 96 NDA approvals and 104 supplement approvals annually, we estimate there will be 200 instances 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. Based upon informal communications with industry and our experience with the collection, we estimate it will take 5 hours to complete Form FDA 3542.

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 comply with 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 such declarations (241 × 3.4 declarations per instance = 819). Based upon informal communications with industry and our experience with the collection, we estimate it will take 20 hours to complete Form FDA 3542a.

Dated: August 5, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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