3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10069 Medicare Waiver Demonstration Application

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Waiver Demonstration Application; *Use:* The currently approved application has been used for several congressionally mandated and Administration high priority demonstrations. The standardized format is not controversial and will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable us to select proposals that meet our objectives and show the best potential for success. *Form Number:* CMS–10069 (OCN: 0938–0880); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 6,000 (For policy questions regarding this collection contact Steven Johnson at 410–786–3332).

Dated: September 11, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–22516 Filed 9–16–13; 8:45 am]

BILLING CODE 4120–01–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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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.

DATES: Fax written comments on the collection of information by October 17, 2013.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.'' 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, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Forms FDA 3542 and 3542a.

The reporting burden for submitting an NDA, an amendment, or a 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 reestimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained in the following paragraphs, 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 FDA 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 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 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 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.

In the **Federal Register** of June 17, 2013 (78 FR 36193), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from a private citizen. The comment stated, generally, that ''it would be appropriate to require, along with the submission of any patents on the original drug and its formulation, any associated patents or claimed patent submission on metabolites or secondary products of the original drugs.''

(FDA Response) FDA disagrees with the comment. FDA's regulations at § 314.53(b) prohibit submission of drug substance (active ingredient) patents claiming metabolites when the metabolite is not the active ingredient described in the NDA. Section 314.53(b) states, in relevant part: ''For patents that claim the drug substance, the applicant shall submit information only on those patents that claim the drug substance that is the subject of the pending or approved application or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application. . . . Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA.'' FDA clarified the criteria for listing patent information in the Orange Book in response to a request by the Federal Trade Commission (FTC) in its July 2002 report on ''Generic Drug Entry Prior to Patent Expiration: An FTC Study'' (see 68 FR 36676; June 18, 2003, and *http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf*). FDA determined that a patent claiming a metabolite does not claim an approved drug and thus does not meet the statutory requirements for listing in the Orange Book (see 67 FR 65448 at 65451; October 24, 2002). However, if a patent claims an approved method of using an approved drug to administer a metabolite, the submission of the patent would be permissible as long as all of the conditions for submitting ''method-of-use'' patents are met (see 68 FR 36676 at 36680; June 18, 2003). Section 314.53(c)(2)(i)(M)(*4*) and 314.53(c)(2)(ii)(N)(*4*) require that an applicant submit on Forms FDA 3542a or 3542, as appropriate, information on whether a drug substance patent claims only a metabolite of the active ingredient that is described in the application or supplement, so that FDA can determine whether the patent is eligible for listing in the Orange Book (see section 2.5 of Forms FDA 3542a and 3542).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.50 (citing § 314.53)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3542	183	2.8	512	5	2,560
Form FDA 3542a	201	2.8	563	20	11,260
Total					13,820

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

The numbers of patents submitted to FDA for listing in the Orange Book in 2010, 2011, and 2012 were 351, 329, and 458, respectively, for an annual average of 379 (351 patents + 329 patents + 458 patents)/3 years = 379 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 53 (379 patents × 14 percent) patents will be multiple listings, and there will be a total of 432 patents (379 patents + 53 patents = 432 patents) declared on Form FDA 3542. We approved 84, 93, and 86 NDAs in 2010, 2011, and 2012, respectively, of which 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, 83, and 101 NDA supplements in 2010, 2011, and 2012, respectively, for which submission of a patent declaration would be required. We estimate there will be 183 instances (based on an average of 88 NDA approvals and 95 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 2.8 declarations (432 patent declarations + 76 no relevant patent declarations)/183 instances = 2.8 declarations per instance) on Form FDA 3542. We filed 96, 91, and 112 NDAs in 2010, 2011,

and 2012, respectively, and 100, 91, and 112 NDA supplements in 2010, 2011, and 2012, respectively, for which submission of a patent declaration would be required. We estimate there will be 201 instances (based on an average of 100 NDAs filed and 101 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 563 declarations (201 instances × 2.8 declarations per instance = 563 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 FDA Forms 3542 and 3542a will be approximately 5 hours and 20 hours per response, respectively.

Dated: September 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22540 Filed 9–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on October 24, 2013, from 8 a.m. to 5 p.m.

Location: Sheraton Silver Spring Hotel, Cypress Ballroom, 8777 Georgia Ave., Silver Spring, MD. The hotel phone number is 301–589–0800.

Contact Person: Karen Abraham-Burrell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AVAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 205123, simeprevir (a hepatitis C virus protease inhibitor), manufactured by Janssen Pharmaceutical Co., with a proposed indication for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin (two medicines approved to treat chronic hepatitis C) in adult patients with compensated liver disease (including cirrhosis) who are treatment-naïve or who have failed previous interferon therapy (pegylated or non-pegylated) with or without ribavirin. Compensated liver disease is a stage in which the liver is damaged but maintains ability to function.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 9, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 1, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 2, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Abraham-Burrell at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 11, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–22546 Filed 9–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning