related to the HPOG 2.0 National Evaluation in the future. A **Federal Register** Notice will be published, allowing for public comment prior to submitting the proposed ICR to OMB.

Respondents: For the HPOG 2.0 National Evaluation: HPOG program managers; HPOG program staff; and representatives of partner agencies and stakeholders, including support service providers, education and vocational training providers, Workforce Investment Boards, TANF agencies, and participants at the 27 non-tribal HPOG 2.0 grantees. For the HPOG 2.0 Tribal Evaluation: Tribal HPOG 2.0 program staff; administrative staff at grantee institutions; representatives from partner agencies and stakeholders, including local employers; and Tribal HPOG program participants at the 5 tribal HPOG 2.0 grantees.

This information collection request is for 3 years.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
HPOG 2.0 National Evaluation					
1. Screening tool for identifying respondents for first-round telephone interviews	114	38	1	.5	19
2. First round telephone interview protocol for non-tribal HPOG grantee staff and partners	570	190	1	.75	143
3. On-site interviews with program management, staff and major partners at six programs	216	72	1	1.5	108
4. Participant contact update forms	15,000	5000	4	.1	2000
HPOG 2.0 Tribal Evaluation					
5. Grantee and partner administrative staff interview	105	35	1	1	35
6. Program implementation staff interview	150	50	1	1.5	75
7. Employer interview	90	30	1	.75	23
8. Program participant focus group	405	135	1	1.5	203
9. Program participant completer interview	300	100	1	1	100
10. Program participant non-completer interview	150	50	1	1	50

Estimated Total Annual Burden Hours: 2756.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF/OPRE Certifying Officer.

[FR Doc. 2016–19337 Filed 8–12–16; 8:45 am]

BILLING CODE 4184–72–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 September 14, 2016.

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	Number of respondents	Number 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.

[FR Doc. 2016–19385 Filed 8–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Facilitating Anti-Infective Drug Development for Neonates and Young Infants; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding anti-infective drug development for neonates and young infants. FDA is interested in discussing the scientific challenges pertaining to development of anti-infective products for neonates and young infants. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, public health organizations, academic experts, and industry on various aspects of drug development for new and currently marketed anti-infective drugs for neonates and young infants. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on September 15, 2016, from 8:30 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301–589–0800.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding anti-infective drug development for neonates and young infants. Discussions will focus on challenges related to enrolling neonates and young infants in clinical trials, strategies to assess central nervous system (CNS) penetration of the drug, including nonclinical and in vitro data, potential development pathways, and the role of clinical trial networks in anti-infective drug development in the neonatal population.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to *NeonatalAntibacterialWorkshop2016@fda.hhs.gov*. Persons without access to the Internet can call 301–796–1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Agenda: The workshop draft Agenda will be made available at: *http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm* at least 2 days prior to the meeting. The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov*. Transcripts will also be available on the Internet at: *http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm* approximately 45 days after the workshop.

Dated: August 8, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

[FR Doc. 2016–19336 Filed 8–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on October 27, 2016, from 1 p.m. to 4:20 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

FOR FURTHER INFORMATION CONTACT: Janie Kim or Denise Royster, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 301–796–9016 or 240–402–8158, email: *Janie.Kim@fda.hhs.gov* or *Denise.Royster@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