

Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection of information includes requirements that are necessary for CMS to conduct compliance review activities. *Form Number:* CMS-10430 (OMB Control Number: 0938-0702); *Frequency:* Annually; *Affected Public:* Private Sector, State or local governments; *Number of Respondents:* 983; *Number of Responses:* 100,759; *Total Annual Hours:* 2,555. (For policy questions regarding this collection, contact Russell Tipps at (301) 492-4371).

Dated: February 25, 2016.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.
 [FR Doc. 2016-04462 Filed 2-29-16; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Directory of New Hires.
OMB No.: 0970-0166.
Description: The National Directory of New Hires (NDNH) is a centralized directory maintained by the Federal Office of Child Support Enforcement. The information maintained in the NDNH is collected electronically and used to help child support agencies in locating parents and enforcing child support orders. Also, Congress authorized specific State and Federal agencies to receive NDNH information for authorized purposes to assist in administering certain programs. The

NDNH is authorized under 42 U.S.C. 653(i)(1).
 The information collection activities pertaining to the NDNH are authorized by:
 (1) 42 U.S.C. 653A(b)(1)(A) and (B), requiring employers to report all newly-hired employees to the State Directory of New Hires (SDNH);
 (2) 42 U.S.C. 653A(g)(2)(A), requiring every SDNH to transmit the new hire information to the NDNH within three business days of the data being entered in the SDNH;
 (3) 26 U.S.C. 3304(a)(16)(B), requiring the reporting of wage and unemployment compensation information contained in the records of agencies administering the State program under part A of title IV of the Social Security Act; and
 (4) Requiring the quarterly reporting of wages and other compensation under—
 • 42 U.S.C. 653A(g)(2)(B), by every SDNH; and
 • 42 U.S.C. 503(h)(1)(A), by State agencies administering the State's unemployment laws.
Respondents: Employers, State IV-A Agencies, State Child Support Agencies, and State Workforce Agencies.

Respondents

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| New Hire: Employers Reporting Manually | 5,130,348 | 1.40 | .025 hours (1.5 minute) | 179,562.18 |
| New Hire: Employers Reporting Electronically | 595,812 | 88.62 | .00028 hours (1 second) | 14,784.24 |
| New Hire: States | 54 | 133,333.33 | .016667 hours (1 minute) | 120,002.40 |
| QW & UI | 53 | 26.00 | .00028 hours (1 second) | 0.39 |
| Multistate Employer Form | 5,127 | 1.00 | .050 hours (3 minutes) | 256.35 |
| Estimate Total Annual Burden Hours | | | | 314,606 |

Estimated Total Annual Burden Hours: 314,606 hours.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the

Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 2016-04410 Filed 2-29-16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0567]

Pediatric Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of February 19, 2016. The amendment is being made to reflect a

change in the *Location* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240-402-3838, email: marieann.brill@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 19, 2016 (81 FR 8508), FDA announced that a meeting of the Pediatric Advisory Committee would be held on April 12, 2016. On page 8508, in the first column, the *Location* portion of the document is changed to read as follows:

DoubleTree by Hilton Hotel Bethesda-Washington DC, 8120 Wisconsin Ave., Bethesda, MD 20814, 301-652-2000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-bethesda-washington-dc-WASBHDT/index.html>.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-04360 Filed 2-29-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-E-1234]

Determination of Regulatory Review Period for Purposes of Patent Extension; INVOKANA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INVOKANA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and

Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by May 2, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 29, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-E-1234 for "Determination of Regulatory Review Period for Purposes of Patent Extension; INVOKANA". Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION: