health-related administrative and other records. In 2017 the NHIS will collect information from approximately 45,000 households, which contain about 100,000 individuals. Information is collected using computer assisted personal interviews (CAPI).

A core set of data is collected each year that remains largely unchanged, whereas sponsored supplements vary from year to year. The core set includes socio-demographic characteristics, health status, health care services, and health behaviors. For 2017, supplemental questions will be cycled in pertaining to alternative and integrative medicine, cognitive disability, receipt of culturally and linguistically appropriate health care services, epilepsy, and heart disease and stroke. Supplemental topics that continue or are enhanced from 2016 pertain to the Affordable Care Act, chronic pain, diabetes, disability and functioning, family food security, ABCS of heart disease and stroke prevention, hepatitis B/C screening, immunizations, smokeless tobacco and e-cigarettes, vision, and children's mental health. Questions from 2016 on balance, Crohn's disease and colitis, and blood donation have been removed. In addition to these core and supplemental modules, a subsample of NHIS respondents and/or members of commercial survey panels may be identified to participate in short, Web-based methodological and cognitive testing activities that will inform the upcoming 2018 NHIS questionnaire redesign. The aims of these standalone assessments include pilot testing new and/or updated questionnaire items, evaluating the impact of different categorical response option formats on answer choices, and measuring respondent comprehension of health care-related terms and concepts.

In accordance with the 1995 initiative to increase the integration of surveys within the DHHS, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, academic, and private researchers to evaluate both general health and specific issues, such as smoking, diabetes, health care coverage, and access to health care. It is a leading source of data for the Congressionally-mandated ''Health US'' and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2020.''

There is no cost to the respondents other than their time. The total estimated annualized burden hours are 49,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Family Member	Family Core	45,000	1	23/60
Sample Adult	Adult Core	36,000	1	15/60
Adult Family Member	Child Core	14,000	1	10/60
Adult Family Member	Supplements	45,000	1	20/60
Adult Family Member	Methodological Projects	15,000	1	20/60
Adult Family Member	Reinterview Survey	5,000	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–28641 Filed 11–28–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Center for States Evaluation Ancillary Data Collection.

OMB No.: New Collection.

Description: The Evaluation of the Child Welfare Capacity Building Collaborative, Center for States is sponsored by the Children's Bureau, Administration for Children and Families of the U.S. Department of Health and Human Services. The purpose of this evaluation is to respond to a set of cross-cutting evaluation questions posed by the Children's Bureau. This new information collection is an ancillary part of a larger data collection effort being conducted for the evaluation of the Child Welfare Capacity Building Collaborative. Two groups of instruments for the larger evaluation have already been submitted, and requests for clearance have been submitted to the Office of Management and Budget (see **Federal Register** Volume 80, No. 211, November 2, 2015; **Federal Register** Volume 81, No. 41, March 2, 2016; **Federal Register** Volume 81, No. 111, June 9, 2016; **Federal Register** Volume 81, No. 186, September 26, 2016), with the first group of instruments approved on August 31, 2016. This notice details a group of instruments that are specific only to the Center for States. The instruments focus on (1) evaluating an innovative approach to engaging professionals in networking and professional development through virtual conferences, (2) understanding fidelity to and effectiveness of the Center for States' Capacity Building Model, and (3) capturing consistent information during the updated annual assessment process focused on related contextual issues impacting potential service delivery such as implementation of new legislation.

Respondents: Respondents of these data collection instruments will include child welfare agency staff and stakeholders who directly receive services.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Virtual Conference (VC) Session Surveys	450	6	.08	216
VC Focus Group Guide	30	1	1	30
VC Interview Guide	20	1	.5	10
VC Registration Data	1000	1	.03	30
Tailored Services Practice Model Survey	130	1	.25	32.5
Assessment Observation—group debrief	50	1	.25	12.5
Service Delivery and Tracking and Adjustment Observation—group debrief	45	1	.25	11.3
Assessment and Service Delivery and Tracking and Adjustment State Lead Interviews	20	1	.5	10
Annual Assessment Update (8 systematic questions)	54	1	.08	4.3

Estimated Total Annual Burden Hours: 356.6.

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: ACF Reports Clearance Officer. Email address: *infocollection@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,

Reports Clearance Officer.

[FR Doc. 2016–28678 Filed 11–28–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–4669 and FDA–2015–E–4659]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IXINITY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 30, 2017. 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 May 30, 2017. 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: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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 Nos. FDA–2015–E–4669 and FDA–2015–E–4659 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; IXINITY.'' Received comments will be placed in the dockets and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets