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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–0214]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Health Interview Survey (NHIS) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 21, 2017. CDC received eight comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Health Interview Survey (NHIS) (OMB Control Number 0920–0214, Expiration Date 12/31/2019)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C.), as amended, authorizes that the Secretary of Health and Human Services (HHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The annual National Health Interview Survey (NHIS) is a major source of general statistics on the health of the U.S. population and has been in the field continuously since 1957. This voluntary and confidential household-based survey collects demographic and health-related information from a nationally-representative sample of households and noninstitutionalized, civilian persons throughout the country. NHIS data have 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. The survey is also 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 Departmental health objectives.

The 2018 NHIS questionnaire remains largely unchanged from its 2017 version, with the exception of new supplements that are being added on asthma and cancer control. These supplements replace those from 2017 on receipt of culturally and linguistically appropriate health care services, diabetes, epilepsy, cognitive disability, complementary health, hepatitis B/C screening, vision, and heart disease and stroke prevention. Continuing from 2017 are supplemental questions about access to and utilization of care and barriers to care, disability and functioning, family food security, ABCS of heart disease and stroke prevention, immunizations, smokeless tobacco and e-cigarettes, and children's mental health.

In addition, in the last quarter of 2018, a portion of the regular 2018 NHIS sample will be used to carry out a dress rehearsal and systems test of the redesigned NHIS questionnaire that is scheduled for launch in January 2019. The redesigned questionnaire revises the NHIS both in terms of content and structure in order to (1) improve the measurement of covered health topics, (2) reduce respondent burden by shortening the length of the questionnaire and seamlessly integrating supplements, (3) harmonize overlapping content with other federal health surveys, (4) establish a long-term structure of ongoing and periodic topics, and (5) incorporate advances in survey methodology and measurement.

As in past years, and in accordance with the 1995 initiative to increase the integration of surveys within the DHHS, respondents to the 2018 NHIS will serve as the sampling frame for the Medical Expenditure Panel Survey. In addition, a subsample of NHIS respondents and/or members of commercial survey panels may be identified to participate in cognitive testing and methodological projects, using web and/or mail survey tools, that will inform the development of new rotating and supplemental content.

There is no cost to the respondents other than their time. Clearance is sought for three years, to collect data for 2018–2020, with an estimated annualized burden of 47,735 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Household Member	Main Household Composition and Family Core.	39,375	1	23/60
Sample Adult	Main Adult Core	31,500	1	15/60
Adult Family Member	Main Child Core	12,250	1	10/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adult Family Member	Main Supplements	39,375	1	20/60
Adult Household Member	Redesigned Household Roster	5,625	1	5/60
Sample Adult	Redesigned Adult Questionnaire	4,500	1	39/60
Adult Family Member	Redesigned Child Questionnaire	1,750	1	27/60
Adult Family Member	Methodological Projects	15,000	1	20/60
Adult Family Member	Main Reinterview Survey	4,375	1	5/60
Adult Family Member	Redesigned Reinterview Survey	625	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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2181]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for XURIDEN 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 January 29, 2018. 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 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2016–E–2181 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; XURIDEN.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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,