DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–0214; Docket No. CDC–2017–0063]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the National Health Interview Survey (NHIS). The annual National Health Interview Survey is a major source of general statistics on the health of the U.S. population.

DATES: Written comments must be received on or before October 20, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0063 by any of the following methods:

• Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

• Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited 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) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

National Health Interview Survey (NHIS) (OMB Control No. 0920–0124, Exp. 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 Act (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, epilepsy, cognitive disability, complementary health, hepatitis B/C screening, vision, and heart disease and stroke prevention. Continuing from 2017 are questions about access to and utilization of care and barriers to care, chronic pain, diabetes, 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 short, Web-based methodological and cognitive testing activities to evaluate the redesigned questionnaire and/or inform the development of new rotating and supplemental content using Web and/or mail survey tools.

There is no cost to the respondents other than their time. Clearance is sought for three years, to collect data for 2018–2020.

**ESTIMATED ANNUALIZED BURDEN HOURS**

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<tr>
<th>Type of respondent</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden (in hours)</th>
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**


**DETERMINATION OF REGULATORY REVIEW PERIOD FOR PURPOSES OF PATENT EXTENSION; RECUVYRA**

**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 RECUVYRA 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 animal 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 October 20, 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 February 20, 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 October 20, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 20, 2017. 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