

Leroy A. Richardson,

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[FR Doc. 2017-17581 Filed 8-18-17; 8:45 am]

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## 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 (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

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adult Household Member .....	Main Household Composition and Family Core	39,375	1	23/60	15,094
Sample Adult .....	Main Adult Core .....	31,500	1	15/60	7,875
Adult Family Member .....	Main Child Core .....	12,250	1	10/60	2,042
Adult Family Member .....	Main Supplements .....	45,000	1	20/60	15,000
Adult Household Member .....	Redesigned Family Core .....	5,625	1	23/60	2,156
Sample Adult .....	Redesigned Adult Core .....	4,500	1	15/60	1,125
Adult Family Member .....	Redesigned Child Core .....	1,750	1	10/60	292
Adult Family Member .....	Methodological Projects .....	15,000	1	20/60	5,000
Adult Family Member .....	Reinterview Survey .....	5,000	1	5/60	417
Total .....	.....	.....	.....	.....	49,000

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA–2013–E–0264; FDA–2013–E–0263; and FDA–2013–E–0218]

**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