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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