in-person survey of 210 incarcerated individuals. A purposive sample of participants will be chosen from each group. Gay and lesbian individuals will be oversampled in the MT group. The incarcerated group will be equally stratified if individuals are intimate partner violence (IPV) offenders or not. Data analysis will include a combination of Factor Analysis and Latent Profile Analysis.

OMB approval is requested for two years for this new collection. Findings from this data collection will be used to understand and identify classes of intimate partner violence (IPV) perpetrators based on shared characteristics such as their personal attributes, risk factors, relationship characteristics, and characteristics of the violence they commit.

The estimated annual burden hours are 1,322. There are no costs to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mechanical Turk Survey Respondents	Screener Survey	4,300	1	5/60
Mechanical Turk Survey Respondents	Understanding Relationship Dynamics and Conflict Survey.	1,000	1	50/60
Incarcerated Survey Respondents	Understanding Relationship Dynamics and Conflict Survey.	105	1	1.25

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. 2017–07960 Filed 4–19–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–17ABE; Docket No. CDC–2017–0034]

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 efforts 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, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection plan titled ''Developmental Projects to Improve the National Health and Nutrition Examination Survey and Related Programs Generic.'' This generic clearance request covers projects that will help evaluate and improve upon issues such as survey design and operations, as well as examine the feasibility and challenges that may arise with developing future content for the National Health and Nutrition Examination Survey (NHANES) (OMB# 0920–0950, expires December 31, 2019) or similar studies.

DATES: Written comments must be received on or before June 19, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2017–0034 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 the 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

Developmental Projects to Improve the National Health and Nutrition Examination Survey and Related Programs Generic—New—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. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability; environmental, social and other health hazards; and determinants of health of the population of the United States. The Division of Health and Nutrition Examination Surveys (DHNES) has conducted national surveys and related projects periodically between 1970 and 1994, and continuously since 1999.

The mission of DHNES programs is to produce descriptive statistics which measure the health and nutrition status of the general population. The continuous operation of DHNES programs presents unique challenges in testing new survey content and activities, such as outreach or participant screening etc.

This generic request covers developmental projects to help evaluate and enhance DHNES existing and proposed data collection activities to increase research capacity and improve data quality. The information collected through this Generic Information Collection Request will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings from these projects may be reported.

The purpose and use of projects under this NHANES generic clearance would include developmental projects necessary for activities such as testing new procedures, equipment, and approaches that are going to be folded into NHANES; designing and testing examination components or survey questions; creating new studies including biomonitoring and clinical measures; creating new cohorts, including a pregnancy and/or a birth—24 month cohort; testing of the cognitive and interpretive aspects of survey methodology; feasibility testing of proposed new components or modifications to existing components; testing of human-computer interfaces/usability; assessing the acceptability of proposed NHANES components among likely participants; testing alternative approaches to existing NHANES procedures, including activities related to improving nonresponse; testing the use of or variations/adjustments in incentives; testing content of Web based surveys; testing the feasibility of obtaining bodily fluid specimens (blood, urine, semen, saliva, breastmilk) and tissue sample (swabs); testing digital imaging technology and related procedures (*e.g.,* retinal scan, liver ultrasound, Dual-energy X-ray absorptiometry (DEXA), prescription and over-the-counter dietary supplements bottles); testing the feasibility of and procedure/processes for accessing participant's medical records from healthcare settings (*e.g.,* hospitals and physician offices); testing the feasibility and protocols for home examination measurements; testing survey materials and procedures to improve response rates, including changes to advance materials and protocols, changes to the incentive structure, introduction of new and timely outreach and awareness procedures including the use of social media; conducting crossover studies; creating and testing digital survey materials; conducting customer satisfaction assessments.

The types of participants covered by the NHANES generic may include current or past NHANES participants; family or household members of NHANES participants; individuals eligible to be participants in NHANES, but who did not screen into the actual survey; convenience samples; volunteers; subject matter experts or consultants such as survey methodologist, academic researchers, clinicians or other health care providers; NHANES data or Web site users; members of the general public or individuals abroad who would be part of a collaborative development project or projects between NCHS and related public health agencies in the U.S. and/or abroad.

The type of participant involved in a given developmental project would be determined by the nature of the project. The details of each project will be included in the specific information collection requests under this generic plan.

There is no cost to respondents other than their time. A three year clearance is requested.

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 hours
Individuals, Households, Volunteers, and NHANES participants.	Developmental Projects, Special Study, Focus Group documents.	5,500	1	3	16,500
Subject Matter Experts	Focus Group/ Developmental Project Documents.	15	1	1	15
NHANES Web and Data users	Customer Satisfaction/ Usability Documents.	1,100	2	5/60	183
Total					16,698

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. 2017–07963 Filed 4–19–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by May 22, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0606. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR Part 111; OMB Control Number 0910–0606—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 402(g) of the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) of the FD&C Act provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations will be modeled after current good manufacturing practice (CGMP) regulations for food and may not impose standards for which there are no current, and generally available, analytical methodology. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA may issue regulations necessary for the efficient enforcement of the FD&C Act. In the **Federal Register** of June 25, 2007 (72 FR 34752), (the June 25, 2007, final rule), FDA published a final rule that established, in part 111 (21 CFR part 111), the minimum CGMP necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement.

Records are an indispensable component of CGMP. The records required by FDA's regulations in part 111 provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to ensure the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. In addition, by establishing recordkeeping requirements, FDA can ensure that industry follows CGMP during manufacturing, packaging, labeling, or holding operations. The regulations in part 111 establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling or holding operations.

The recordkeeping requirements of the regulations include establishing written procedures and maintaining records pertaining to: (1) Personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and repackagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses engaged in the dietary supplement industry.

The recordkeeping requirements of the regulations in part 111 are set forth in each subpart. In table 1, we list the annual burdens associated with recordkeeping, as described in the June 25, 2007, final rule. For some provisions listed in table 1, we did not estimate the number of records per recordkeeper because recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. When the records burden involves frequent brief entries, we entered 1 as the default for the number of records per recordkeeper. For example, many of the records listed under § 111.35 in table 1, such as § 111.35(b)(2) (documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment), involve many