October 20, 2010, from 8:30 a.m. until 5:15 p.m.

ADDRESSES: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Hubert H. Humphrey Building, Room 800, Washington, DC 20201.

FOR FUTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; *fax:* 240–453–6909; *e-mail address: Julia.Gorey@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On October 19, 2010, SACHRP will hear a panel of four experts discuss the evolving concepts of identifiability and anonymization of data in the context of current and future research. Following the panel, the Subcommittee on Harmonization (SOH) will present a report. The SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

On October 20, 2010, the morning will begin with a panel discussing the use of deception in human subjects research. Subpart A Subcommittee (SAS) will make a report focusing on improvements to the informed consent process. SAS is charged with developing recommendations for consideration by SACHRP about the application of subpart A of 45 CFR part 46 in the current research environment. This subcommittee was established by SACHRP at its October 2006 meeting. Public comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business Friday, October 15, 2010.

Dated: September 21, 2010.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2010–24128 Filed 9–24–10; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–10–10GY]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Community Assessment and Engagement Process—New—Division of Health Assessment and Consultation (DHAC), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

ATSDR serves the public through responsive public health actions to promote healthy and safe environments and to prevent harmful exposures. To effectively implement ATSDR's programs, the agency works with communities by listening to and understanding their health concerns and seeking their guidance on where, when, and how to take public health actions. Communities in proximity to hazardous waste sites are concerned that they are being exposed to hazardous substances being released into the environment. Community assessment data will enable ATSDR to determine the perceived needs, concerns, values, and priorities of communities we serve and determine their willingness, interest and ability to participate in community engagement activities.

In order to secure this data, ATSDR will interview adult males and females ages 18 and over living near petitioned or National Priorities List sites. ATSDR will also identify health and other concerns and the most effective channels of communication and venues for engagement.

ATSDR staff will work with key stakeholders in communities to interview participants. These interviews will take the form of in-depth or telephone interviews with five audiences: General residential population (n = 600), public/private health care providers (n = 200), community leaders (n = 200), elected officials (n = 100), and industry leaders (n = 100).

In-depth Interviews will take place at the individual's residence, at a predetermined interview location, at ATSDR-sponsored town hall meetings, or other ATSDR-sponsored functions. Telephone interviews will take place at the individual's residence or business location. Findings from these interviews will be used to determine how ATSDR will engage the community in addressing environmental concerns. Interview findings will also help ATSDR reach as many of the members of the affected community as possible and ensure that all community members are given an opportunity to provide input to ATSDR regarding public health assessment and community involvement activities. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)	Total burden hours
General Resident	In-depth Interview/phone	600	1	1.5	900
	Screener	1,200	1	6/60	120
Health care provider	In-depth Interview/phone	200	1	.5	100
	Screener	400	1	6/60	40
Community Leader	In-depth Interview/phone	200	1	1.5	300
	Screener	400	1	6/60	40
Elected Official	In-depth Interview/phone	100	1	.5	50
Industry	In-depth Interview/phone	100	1	.5	50
Total					1,600

Dated: September 21, 2010.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–24181 Filed 9–24–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0355]

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.

DATES: Fax written comments on the collection of information by October 27, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 (OMB Control Number 0910–0606)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 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 (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the FD&C Act also stipulates that such regulations shall be modeled after current good manufacturing practices (CGMPs) 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), FDA may issue regulations necessary for the efficient enforcement of the FD&C Act. FDA published a final rule on June 25, 2007 (72 FR 34752) (the final rule) that established, in part 111 (21 CFR part 111), the minimum CGMPs 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 CGMPs. 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 CGMPs. The records will show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to control 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 requiring records, FDA will be able to ensure that industry follows CGMPs 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 records requirements of the regulations include written procedures and 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