Respondents	Number of respondents	Number of responses/respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
General public responding to on-line survey	1000	1	.25	250
Users of www.cdc.gov responding to a bounce back form	10,000	1	.20	2,000
TOTAL				2,250

Dated: February 28, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–5131 Filed 3–2–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–00–25]

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, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

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 for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Evaluation of ATSDR Activities Among Priority Populations—New—The Agency for Toxic Substances and Disease Registry (ATSDR) is mandated pursuant to the 1980 Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and its 1986 Amendments, The Superfund Amendments and Re-authorization Act (SARA), to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances into the environment.

As the agency responsible for determining the nature and extent of health problems at Superfund sites, ATSDR staff conduct public health assessments, health consultations and studies that serve as the basis for intervention strategies. ATSDR staff develop and disseminate to the public scientific and technical reports on the health effects of hazardous substances. Additionally, ATSDR staff collaborate with other governmental agencies, external partners and organizations to create and implement health services, educational and preventive programs.

To date, however, ATSDR has not conducted agency-wide quantitative research to evaluate the effectiveness of its services, products and programs. ATSDR staff is seeking information from its priority populations to determine their awareness of, access to and utilization of ATSDR products, programs and services. ATSDR staff will also evaluate whether priority populations derived health benefits from interventions.

ATSDR's priority populations include individuals, health care providers, health department officials and members of community organizations who live within two miles of National Priority Sites. Randomly stratified samples of individuals in these priority populations will be selected and asked to answer a questionnaire on two separate occasions within the three-year project. The questionnaire will be designed to use Computer Assisted Telephone Interviews (CATI) so that respondent burden can be reduced.

ATSDR will use the data from this study to evaluate and improve the effectiveness of health promotion and intervention activities in communities. This will translate into more effective organizational decisions on resource utilization, improved performance, and assessment of the future direction of the agency. There is no cost to the respondents.

Respondents	No. of respondents per year	No. of responses per respondent	Avg. burden per response (in hrs.)	Total annual burden (in hrs.)
Individuals in priority populations	6,667	1	.33	2,200

2. Emergency Epidemic Investigations–(0920–0010)—Renewal—(Epidemiology Program Office, EPO)—One of the objectives of CDC's epidemic services is to provide for the prevention and control of epidemics and protect the population from public health crises such as man made or natural biological disasters and chemical emergencies. This is carried out, in part, by training investigators, maintaining laboratory capabilities for identifying potential problems, collecting and analyzing data, and recommending appropriate actions to protect the public's health. When state, local, or foreign health authorities request help in controlling an epidemic or solving other health problems, CDC dispatches skilled epidemiologists from the Epidemic Intelligence Service (EIS) to investigate and resolve the problem. Resolving public health problems rapidly ensures costs effective health care and enhances health promotion and disease prevention. Annually, the EIS Program coordinates 400 Epidemic Assistance Investigations (Epi-Aids) and state-based field investigations. Epidemics are prevented and controlled by mobilizing and deploying CDC staff, primarily EIS officers to respond rapidly to disease outbreaks and disaster situations. At the request of public

health officials—at the state, national, or international level–CDC provides assistance by participating in epidemiologic field investigations. The purpose of the Emergency Epidemic Investigation surveillance is to collect data on the conditions surrounding and preceding the onset of a problem. The data must be collected in a timely fashion so that information can be used to develop prevention and control techniques, to interrupt disease transmission and to help identify the cause of an outbreak. Since the events necessitating the collections of information are of an emergency nature, most data collection is done by direct interview or written questionnaire and are one-time efforts related to a specific outbreak or circumstance. If during the emergency investigation, the need for further study is recognized, a project is designed and separate OMB clearance is required. Interviews are conducted to be as unobtrusive as possible and only the minimal information necessary is collected. The Emergency Epidemic Investigations is the principal source of data on outbreaks of infectious and noninfectious diseases, injuries, nutrition, environmental health and occupational problems.

Each investigation does contribute to the general knowledge about a particular type of problem or emergency, so that data collections are designed taking into account similar situations in the past. Some questionnaire have been standardized, such as investigations of outbreaks aboard aircraft or cruise vessels.

The Emergency Epidemic Investigations provides a range of data on the characteristics of outbreaks and those affected by them. Data collected include demographic characteristics, exposure to the causative agent(s), transmission patterns and severity of the outbreak on the affected population. These data, together with trend data, may be used to monitor the effects of change in the health care system, planning of health services, improving the availability of medical services and assessing the health status of the population.

Users of the Emergency Epidemic Investigations data include, but are not limited to EIS Officers in investigating the patterns of disease or injury, investigating the level of risky behaviors, identifying the causative agent and identifying the transmission of the condition and the impact of interventions.

It is difficult to predict the number of epidemic investigations which might occur in any given year. The previous three years' experience shows an annualized burden of 2,304 hours and respondent total of 10,150. Therefore, the request is for an estimated annual burden of 3,000 hours. This represents an estimated 12,000 respondents annually at 15/60 hours per response. There are no costs to respondents other than time.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden per response (in hrs.)	Total Burden (in hrs.)
Total Respondents	12,000	1	15/60	3,000

3. 2nd Injury Control and Risk Survey (ICARIS2)—New—The National Center for Injury Prevention and Control (NCIPC)—This project will use data from a telephone survey to measure injury-related risk factors and guide injury prevention and control priorities, including those identified as priorities in *Healthy People 2010* objectives for the nation. Injuries are a major cause of premature death and disability with associated economic costs over 150 billion dollars in lifetime costs for persons injured each year. *Healthy People 2010* objectives and the recent report from the Institute of Medicine, *Reducing the Burden of Injury,* call for reducing this toll. In addition to national efforts, NCIPC funds injury control programs at the state and local levels. These programs need data both to establish their prevention priorities and monitor their performance. The use of outcome data (*e.g.,* fatal injuries) for measuring program effectiveness is problematic because cause-specific events are relatively rare and because data on critical risk factors (*e.g.,* was a helmet worn in a fatal bike crash, was a smoke detector present at a fatal fire?) are often missing. Because these risk factors are early in the causal chain of injury, they are what injury control programs target to prevent injuries. Accordingly, monitoring the level of injury risk factors in a population can help programs set priorities and evaluate interventions.

The first Injury Control and Risk Survey (ICARIS), conducted in 1994, was a random digit dial telephone survey that collected injury risk factor and demographic data on 5,238 English- and Spanish-speaking adults (≥18 yrs-old) in the United States. Proxy data were collected on 3,541 children <15 years old. More than a dozen peer-reviewed scientific reports have been published from the ICARIS data, on subjects including dog bites, bicycle helmet use, residential smoke detector usage and fire escape practices, attitudes towards violence, suicidal ideation and behavior, and compliance with pediatric injury prevention counseling. Five years have elapsed since ICARIS, and a repeat survey is needed for monitoring the injury risk factor status of the nation at the start of the millennium. Further, by using data collected in ICARIS as a baseline, ICARIS2 can measure changes and gauge the impact of injury prevention policies. ICARIS2 may also serve as the only readily available source of data to measure several of the Healthy People 2010 injury prevention objectives. Total cost to respondent $0.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Adults ≥ 18 y/o	10,000	1	.50	5,000
Total	.....	.....	.....	5,000

4. 2001 National Health Interview Survey, Basic Module (0920–0214)—Revision—The National Center for Health Statistics (NCHS)—The annual National Health Interview Survey (NHIS) is a basic source of general

statistics on the health of the U.S. population. Due to the integration of health surveys in the Department of Health and Human Services, the NHIS also has become the sampling frame and first stage of data collection for other major surveys, including the Medical Expenditure Panel Survey, the National Survey of Family Growth, and the National Health and Nutrition Examination Survey. By linking to the NHIS, the analysis potential of these surveys increases. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, AIDS, and childhood immunizations. Journalists use its data to inform the general public. It will continue to be 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 the National Health Promotion and Disease Prevention Objectives, ''Healthy People 2000.''

Because of survey integration and changes in the health and health care of the U.S. population, demands on the NHIS have changed and increased, leading to a major redesign of the annual core questionnaire, or Basic Module, and a redesign of the data collection system from paper questionnaires to computer assisted personal interviews (CAPI). Those redesigned elements were partially implemented in 1996 and fully implemented in 1997 and are expected to be in the field until 2006. This clearance is for the fifth full year of data collection using the Basic Module on CAPI, and for implementation of the second ''Periodic Module'', which include additional detail questions on conditions, access to care, disabilities, and health care utilization. The ''Periodic Module'' will repeat a similar survey conducted in 1992, and will help track many of the Health People 2010 objectives. This data collection, planned for January-December 2001, will result in publication of new national estimates of health statistics, release of public use micro data files, and a sampling frame for other integrated surveys. The total cost to respondents is estimated at $70,860 for the whole survey.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden per response	Total burden (in hrs.)
Family	42,000	1	0.35	14,700
Sample adult	42,000	1	0.70	29,400
Sample child	18,000	1	0.25	4,500
Total				48,600

Dated: February 28, 2000.

Charles Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–5132 Filed 3–2–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F–0792]

The Procter & Gamble Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Procter & Gamble Co. (P&G) has filed a petition proposing that the food additive regulations regarding olestra be amended by removing the requirement for the label statement.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3102.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (the act) (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4708) has been filed by P&G, Winton Hill Technical Center, 6071 Center Hill Ave., Cincinnati, OH 45224. The petition proposes to amend the food additive regulations in § 172.867 *Olestra* (21 CFR 172.867) by removing the requirement for the label statement prescribed in § 172.867(e).

Olestra is a food additive that is approved for use in place of fats and oils in prepackaged ready-to-eat savory snacks (§ 172.867). Olestra is not digested to any appreciable degree in the human gut and is not absorbed or metabolized by the body.

In the **Federal Register** of June 23, 1987 (52 FR 23606), FDA announced that P&G had filed a petition (FAP 7A3997) proposing that the food additive regulations be amended to provide for the safe use of olestra. FDA subsequently published a final rule approving olestra for use in savory snacks(61 FR 3118, January 30, 1996) after completing its evaluation of the relevant data and information. Prior to the issuance of the final rule, FDA convened a public meeting of its Food Advisory Committee (FAC) on November 14 through 17, 1995, to undertake a scientific discussion of the agency's evaluation of the safety data in the petition. As a result of the 4-day FAC meeting, a substantial portion of the relevant safety data on olestra was publicly discussed in detail by both proponents and opponents of olestra's approval, as well as by members of the FAC.

In issuing the olestra final rule, FDA carefully considered the proper labeling for foods containing the additive. This issue was also discussed in detail before the FAC. As noted, olestra is not absorbed, and it passes through the gastrointestinal (GI) tract intact. Data from clinical studies submitted by P&G in support of its original petition show that consumption of olestra with a meal can affect the absorption of certain fat-soluble vitamins and nutrients, which partition into the olestra. The petitioner and FDA agreed that these fat-soluble vitamins needed to be added to the snacks to compensate for any such effect, and that this addition of vitamins was not equivalent to fortification. These data also show that olestra has the potential to cause certain GI effects such as abdominal cramping and loose stools. FDA determined that consumers needed to know about any potential effects of olestra on the GI system.

In view of the record before the agency, FDA concluded that olestra-containing products would need to carry an information statement in order for such products to avoid being misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n). Therefore, the final rule (§ 172.867(e)) required that foods containing olestra be labeled with the following statement in a boxed