Proposed Project

All Age Influenza Hospitalization Surveillance (Flu Hosp)—New—National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting OMB approval for a data collection system that will assist public health officials to better monitor and assess severe forms of influenza disease resulting in hospitalization. Approval is sought for an Adult Case Report Form and a Pediatric Case Report Form. The Adult Case Report Form will be used to collect information on patients over the age of 18 years old, and the Pediatric Case Report form will be used for patients under 18 years and younger. The primary difference between the two forms is that the Adult Case Report form includes collection of information related to Statin use, and the Pediatric Case Report form does not.

Adult surveillance will consist of two phases, a prospective data collection, and a retrospective discharge audit. Therefore, approval is also sought for forms that will assess the completeness of the surveillance system's cases. These forms make up an Adult discharge audit, which will reveal any limitations in the prospective case identification that will have occurred prior to the discharge audit.

Flu Hosp uses standardized data collection instruments that collect demographic and clinical information from laboratory-confirmed influenza hospitalized adults and children who reside in a geographic- and population-defined area of the United States. The data collection network is an established CDC-state-academic institution collaborative network, the Emerging Infections Program (EIP) which includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.

From October 1 of this year through April 30 of the following year (the current flu season), Flu Hosp collects data and transmits it to CDC. Case reports are submitted as soon as possible after the investigation of a case. Prompt notification to CDC allows for identification of epidemics and outbreaks so that immediate prevention measures can be taken. Most of the data collection instrument can be completed from review of the hospital medical records. If none of these resources are available, the patient or their proxy may be interviewed.

CDC and its participating partners will also perform a discharge audit to assess the completeness of the case surveillance data by conducting an evaluation of the hospitalized influenza cases found by Flu Hosp versus an independent, administrative hospital dataset. Each of the ten participating sites will complete standardized forms that describe the evaluation process and the number of cases missed by Flu Hosp, in aggregate. Although 10 states participate in Flu Hosp, because New York includes two functionally and geographically different catchment areas, those two areas will submit individual discharge audit data, to make a total of 11 respondents.

The respondents for the data collections are the Flu Hosp participating sites. There are no costs to respondents other than their time for participating.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pediatric Influenza Hospitalization Surveillance Project Case Report Form.	Health Department	10	75	15/60	188
Adult Influenza Hospitalization Surveillance Project Case Report Form.	Health Department	10	120	15/60	300
Adult Discharge Audit Case Report Form	Health Department	11	3	15/60	8
Adult Discharge Audit Form A: Description of Matching Method.	Health Department	11	1	15/60	3
Adult Discharge Audit Form B: Sampling Strategy	Health Department	11	1	15/60	3
Adult Discharge Audit Form C: Summary	Health Department	11	1	15/60	3
Adult Discharge Audit Form D: Future	Health Department	11	1	15/60	3
Total	.....	.....	.....	.....	508

Dated: November 19, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22919 Filed 11–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–0692]

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 for 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 Acting 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

A Survey of the Knowledge, Attitudes and Practice of Medical and Allied Health Professionals Regarding Fetal Alcohol Exposure—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, Section 301, which authorizes ''research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.'' (2) 42 U.S.C. 247b–4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as ''the Children's Health Act of 2000.'' This portion of the code has also been amended by Public Law 108–154, which is also known as the ''Birth Defects and Developmental Disabilities Prevention Act of 2003.''

Maternal prenatal alcohol use is one of the leading, preventable, causes of birth defects and developmental disabilities. Children exposed to alcohol during fetal development can suffer a wide array of disorders, from subtle changes in I.Q. and behaviors to profound mental retardation. These conditions are known as fetal alcohol spectrum disorders (FASDs). The most severe condition within the spectrum is fetal alcohol syndrome (FAS), which involves disorders of the brain, growth retardation, and facial malformations.

Physicians and other health practitioners play a vital role in diagnosing FAS and in screening women of child-bearing age for alcohol consumption and drinking during pregnancy. In Diekman's, *et al.* 2000, study of obstetricians and gynecologists, only one-fifth of doctors surveyed reported abstinence to be the safest way to avoid the adverse outcomes associated with fetal alcohol exposure.[3] Importantly, 13% of doctors surveyed were not sure of levels of alcohol consumption associated with adverse outcomes.[3] One of CDC's multifaceted initiatives in combating alcohol-exposed pregnancies is the education and reeducation of medical and allied health students and practitioners.

In fiscal year 2002, the Centers for Disease Control and Prevention (CDC) received a congressional mandate to develop guidelines for the diagnosis of FAS and other conditions resulting from prenatal alcohol exposure; and to incorporate these guidelines into curricula for medical and allied health students and practitioners [Public Health Service Act Section 317K (247b–12) b and c] (See Appendices A–1, A–2, A–3.)

In response to the second congressional mandate listed above, CDC proposed five national surveys of health providers. In August of 2005, OMB approved these five surveys under control number 0920–0692. The purposes of the surveys are to assess, among various health care provider groups, their knowledge, attitudes, and practices regarding the prevention, identification, and treatment of FASDs. These health care provider groups are pediatricians, obstetrician-gynecologists (OB–GYNs), psychiatrists, family physicians, and allied health professionals. To date, three of the five surveys have yet to be conducted—the survey of allied health professionals, the survey of family physicians, and the survey of pediatricians.

The results of the surveys will help to inform further development of model FASD curricula to disseminate among medical and allied health students and professionals nation wide using a variety of formats including computer interactive learning applications, workshops and conferences, Continuing Medical Education credit courses, and medical and allied health school grand rounds and clerkships. Consistent with OMB's previous terms of clearance, CDC does not expect the results to be generalizable to the larger populations of the professional organizations from which the samples were drawn. Instead, the survey results will provide necessary information to further develop and refine educational materials for medical and allied health students and practitioners and to evaluate their effectiveness. No gifts or compensation will be given to respondents who complete the survey. There is no cost to respondents other than their time.

Estimate of Annualized Burden Hours

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Pediatricians	900	1	25/60	375
Obstetrician-Gynecologists	900	1	25/60	375
Psychiatrists	900	1	25/60	375
Family Physicians	900	1	25/60	375
Allied Health Professionals	900	1	25/60	375
Total				

Dated: November 16, 2007.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22920 Filed 11–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–08–06AY]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the Spanish-Language Campaign *''Good Morning Arthritis, Today You Will Not Defeat Us.''*—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Arthritis affects nearly 43 million Americans, or about one in every five people, and is the leading cause of disability among adults in the United States. Limitations due to arthritis are particularly burdensome when they affect an individual's mobility, productivity, and ability to earn a living, as well as psychological and social well-being. Because of the broad public health impact of this disease, the Centers for Disease Control and Prevention (CDC) developed the National Arthritis Action Plan in 1998 as a comprehensive approach to reducing the burden of arthritis in the United States.

Hispanics are currently the fastest growing racial/ethnic group in the United States. Although Hispanic populations have a slightly lower prevalence rate of self-reported, doctor-diagnosed arthritis than the general population, Hispanics with arthritis report greater work limitations, and higher rates of severe pain than do Caucasian populations with arthritis. CDC has developed a Spanish-language campaign, *Good Morning Arthritis, Today you will not defeat us,* to deliver culturally appropriate public health messages about the benefits of physical activity as an arthritis management strategy. Campaign materials include print ads, 30 and 60 second radio ads and public service announcements, and desktop displays with brochures for pharmacies, doctors' offices, and community centers. The campaign is designed to reach Spanish speaking adults with arthritis who are aged 45–64, who have high school education or less, and whose annual income is less than $35,000. CDC plans to conduct the campaign in four experimental markets.

CDC requests clearance to conduct an evaluation of the campaign by collecting information from Spanish-speaking respondents in the four experimental markets and two control markets. An initial data collection will consist of telephone interviews, and will be based on a pre- and post-campaign evaluation design. A follow-up telephone interview, involving a subset of the initial respondents, will be conducted six months later. Results will be used to guide the public health practice of the 36 CDC-funded state arthritis programs and their partners.

There are no costs to respondents other than their time. The estimated annualized burden hours are 2,730.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Target Population of Hispanic Adults	Screener for Primary Pre- and Post Campaign Survey.	60,000	1	2/60
	Primary Pre- and Post Campaign Survey	2,400	1	13/60
	Screener for 6–Month Follow-up Survey	2,400	1	2/60
	6–Month Follow-up Survey	600	1	13/60

Dated: November 16, 2007.

Marilyn S. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–22930 Filed 11–23–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006P–0291, 2006P–0299, 2006P–0298, 2006P–0309, and 2007P–0062]

Determination That ELOXATIN (Oxaliplatin for Injection), 50 and 100 Milligrams Per Vial, Sterile Lyophilized Powder for Injection, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ELOXATIN (oxaliplatin for injection), 50 and 100 milligrams (mg) per vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers