and application forms. The announcement is also available through the CDC home page on the Internet. The address for the CDC home page is http://www.cdc.gov.

If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from Maggie Slay, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842- 6630, or INTERNET address, mcs9@ops.pgo1.em.cdc.gov.

Programmatic technical assistance may be obtained from Sharon Campolucci, Deputy Director, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–31, Atlanta, GA 30333, telephone (404) 639–6200, or INTERNET address, ssc1@atsdhs2.em.cdc.gov.

Please Refer to Announcement Number 607 When Requesting Information and Submitting an Application

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 22, 1996.

Claire V. Broome,

*Deputy Administrator, Agency for Toxic Substances and Disease Registry.*

[FR Doc. 96–10362 Filed 4–25–96; 8:45 am]

BILLING CODE 4163–70–P

## Centers for Disease Control and Prevention

**[INFO–96–14]**

## 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 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 Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Studies of Adverse Reproductive Outcomes in Female Occupational Groups—(0920–0367)—Revised—An estimated 50,000 to 60,000 chemicals are in common use throughout society today and hundreds of new chemicals are introduced each year. Yet the list of environmental chemicals and agents that have been investigated to determine whether they have adverse effects on reproductive health is still limited. With the growing number of women in the work force, it is becoming increasingly important to evaluate the potential female reproductive health effects of occupational and physical agents.

In this program, NIOSH is planning to undertake a series of five studies to focus on potential reproductive effects of chemical and physical agents in the workplace. In the studies planned under this program, the reproductive health of a group of female workers exposed to the agent of interest, will be compared to the reproductive health of a group of working women with no occupational exposure to known or suspected reproductive toxicants.

For all studies, data from company personnel records containing demographic, and work history information will be used to estimate workplace exposures. Each woman will be asked to complete a telephone questionnaire on reproductive history and other factors (such as cigarette smoking) that may influence reproductive function. Each questionnaire will take approximately 60 minutes to complete. Medical records will be requested to confirm adverse reproductive outcomes reported by the participants. The risk of adverse reproductive outcomes between the two groups of women will then be compared.

The first study to be conducted under this program will be a study of reproductive disorders among female flight attendants. Approximately 66,000 flight attendants are currently employed by U.S. commercial airlines and are potentially exposed to ionizing radiation and disruption of circadian rhythms, two exposures that may adversely affect reproductive function. The other studies to be conducted under this program have not yet been determined. The total cost to respondents is estimated at 102,000.00

| Respondents | No. of respondents | No. of responses/respondent | Avg. burden/response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Workers | 6,200 | 1 | 1 | 6,200 |
| Medical providers | 1,200 | 1 | 0.5 | 600 |
| Total | ..... | ..... | ..... | 6,800 |

2. Coal Mine Dust Personal Sampling Systems—(0920–148)—Extension—This project, mandated under the Federal Mine Safety and Health Act of 1977 (Pub. L. 91–173, as amended by Pub. L. 95–164), involves conducting evaluations and tests on coal mine dust personnel sampling units (CMDPSUs) and issuing certifications for those CMDPSUs which meet or exceed all applicable requirements listed in 30 CFR Part 74. It also requires conducting audits of new ''off-the-shelf'' CMDPSUs certified under these regulations to determine compliance, evaluating those CMDPSUs sent to NIOSH as field problems, and responding to technical assistance requests. The total cost to respondents is estimated at $11,000.

| Respondents | No. of respondents | No. of responses/respondent | Avg. burden/response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Manufacturer | 1 | 1 | 39 | 39 |
| Total | | | | 39 |

3. Monthly Vital Statistics Report—(0920–0213)—Extension—The compilation of national vital statistics dates back to the beginning of this century and has been conducted since 1960 by the Division of Vital Statistics of the National Center for Health Statistics, CDC. The collection of the data is authorized by 42 USC 242k. The Monthly Vital Statistics Report provides estimates of monthly occurrences of births, deaths, infant deaths, marriages, and divorces following the end of each month. Similar data have been published since 1937, and are the sole source of these data at the national level. The data are widely used by the Department of Health and Human Services and by other government, academic, and private research organizations in tracking changes in trends of vital events. The data are essential to the U. S. Bureau of the Census as input to their various population estimates. They are also used each month by the Bureau of Economic Analysis, Department of Commerce, to extrapolate an element of the Gross National Product.

Respondents for the Monthly Vital Statistics Report and the Monthly Report on Marriages, Divorces and Annulments are registration officials in each state, the District of Columbia, and New York City. Respondents for the Monthly Marriage and Divorce Statistical Report forms are 60 local (county) officials in New Mexico who record marriages occurring and divorces and annulments granted in each county of New Mexico. The are no direct costs to respondents; the data are routinely available in each reporting office as a by-product of ongoing activities.

| Respondents | No. of respondents | No. of responses/respondents | Avg. burden/response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| State registration officials: Monthly Vital Statistics Report | 52 | 12 | 0.1 | 62.4 |
| State registration officials: Monthly Report on Marriages, Divorces, and Annulments | 52 | 12 | 0.1 | 62.4 |
| County registration officials: New Mexico: Monthly Marriage and Divorce Statistical Report Forms | 60 | 12 | 0.1 | 72 |
| Total | | | | 197 |

4. Standardized Reporting System and Associated Epidemiologic Investigations of Occupationally Related Infection with Human Immunodeficiency Virus in Health Care and Public Safety Settings (0920–0286)—Extension—The Surveillance Branch, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention plans to continue surveillance of health care workers (HCWs) and public safety workers who may have occupationally acquired human immunodeficiency virus (HIV) infection. This reporting system, initiated September 1991, collects essential scientific information on workers with occupationally acquired HIV infection, the exposures that led to infection, and the natural history of HIV infection. State and local health departments will investigate reported cases of HCWs and others with HIV infection for whom HIV may have been transmitted through occupational exposures. With the consent of the infected worker, the health department will collect information including: HIV test results; whether the route of exposure was percutaneous, mucous membrane, or skin; the type of device and procedure associated with the exposure; use of postexposure chemoprophylaxis; and other behavioral and transfusion risk factors for HIV infection. Reports, without identifying information, will be forwarded from the health department to CDC. The total cost to respondents is estimated at $1,250.

| Respondents | No. of respondents | No. of responses/respondent | Average burden /response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Workers who may have occupation- ally acquired HIV infection | 100 | 1 | 0.5 | 50 |
| Total | | | | 50 |

5. Development and Implementation of a Comprehensive Evaluation for Project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together—NEW—Diabetes mellitus is more prevalent among African-Americans than whites, and African-Americans with diabetes are more likely to suffer its devastating complications. Compared to whites, African-Americans are more likely to develop blindness and end-stage renal disease and are more likely to have amputations. In addition, cardiovascular risk factors are more prevalent among African-Americans than whites and African-Americans are more likely to die with diabetes than are whites. In response to this disparity, the Centers for Disease Control and Prevention (CDC) has launched a large-scale community intervention trial known as Project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together). Based in Raleigh, North Carolina, and sponsored by CDC's Division of Diabetes Translation, Project DIRECT will serve as a model for multilevel community-based diabetes prevention and control programs for urban African-Americans.

This evaluation will determine the effect of (1) diabetes care; (2) outreach, and (3) health promotion interventions in the targeted community and compare this effect to a control community. The intervention activities focus on the African-American population of a geographically defined area of southeast Raleigh, North Carolina. The control community

is Greensboro, North Carolina. The populations consist primarily of African-Americans. Health care providers will be identified and solicited from practicing physicians in Raleigh and Greensboro.

The survey will be conducted in four phases. Phase I will randomly identify and solicit participation from household members with and without diabetes from the control and intervention communities. In Phase II, participants with and without diabetes will be randomly selected and administered the survey questionnaire upon granting informed consent. During Phase III, persons with diabetes will undergo a brief physical exam that will consist of physical measures for height, weight, blood pressure, and body mass index. In addition, collection of a venous blood sample and urine sample will be performed. In Phase IV, interviewers will administer a questionnaire to primary care physicians about their knowledge, attitude and practice patterns for caring for persons with diabetes. This study will undergo Institutional Review Board reviews and comply with human subject assurances in accordance with federal regulations. The total cost to respondents is estimated at $41,160.

| Respondents | No. of respondents | No. of responses/respondent | Avg. burden/response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Households | 8,000 | 1 | 0.3333 | 2,666 |
| Persons without diabetes | 1,600 | 1 | 0.5 | 800 |
| Persons with diabetes | 600 | 1 | 0.5 | 300 |
| Primary Care Physicians | 140 | 1 | 0.5 | 70 |
| Total | | | | 3,836 |

6. National Disease Surveillance Program I—(0920–0009)—Extension—Formal surveillance of 21 separate reportable diseases has been ongoing to meet the public demand and scientific interest for accurate, consistent epidemiologic data. The diseases include: HIV/AIDS, bacterial meningitis, dengue, idiopathic CD4+ T-lymphocytopenia, kawasaki syndrome, legionellosis, Hansen's Disease, lyme disease, malaria, pertussis, plague, poliomyelitis, psittacosis, Reye Syndrome, Rocky Mountain Spotted Fever, Tetanus, Toxic Shock Syndrome, toxocariasis, trichinosis, typhoid fever, and viral hepatitis. Case report forms enable CDC to collect demographic, clinical, and laboratory characteristics of cases of these diseases. This information is used to direct epidemiologic investigations, to identify and monitor trends in reemerging infectious diseases or emerging modes of transmission, to search for possible causes or sources of the diseases, and to develop guidelines for prevention and or treatment. It is also used to recommend target areas in most need of vaccinations for certain diseases and to determine development of drug resistance.

Because of the distinct nature of each of the diseases, the number of cases reported annually is different for each. The total cost to respondents is estimated at $818,184.

| Respondents | No. of respondents | No. of responses/respondent | Avg. burden response (in hrs.) | Total burden (in hrs.) |
|---|---|---|---|---|
| Health Care Workers | 125,214 | 1 | 0.5 | 34,091 |
| Total | | | | 34,091 |

Dated: April 22, 1996.

Wilma G. Johnson,

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

[FR Doc. 96–10356 Filed 4–25–96; 8:45 am]

**BILLING CODE 4163–18–P**

## Food and Drug Administration

**[Docket No. 96N–0010]**

## Agency Information Collection Activities; Proposed Collection; Comment Request

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of male and female consumers regarding various formats for presenting risk and benefit information in drug labeling.

**DATES:** Submit written comments by June 25, 1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide 60-day notice in the Federal Register concerning each proposed collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of