Dated: August 19, 2003.

Nancy E. Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–63–03]

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) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503; or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project: Work and Health Study: Risk Factors for Heart Disease and Depression in the Workplace—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Cardiovascular disease (CVD) and depression represent health problems of staggering proportion for the United States. An estimated 60 million Americans, over half of whom are younger than 65 years of age, currently have some form of CVD, and nearly 20 percent of all Americans will experience at least one episode of major depression during their lifetimes. In economic terms, the total yearly costs of CVD and depression in the United States have been estimated at $327 billion and $43 billion, respectively.

In addition to being common and costly health problems, CVD and depression co-morbidity is frequent, and recent studies have shown increased cardiovascular morbidity and mortality in depressed patients, implicating depression as a potential independent risk factor for CVD. Understanding the causes and etiologic relationships between these two illnesses represents a major challenge for public health researchers.

In addition to traditionally recognized risk factors, occupational factors appear to play a role in the etiology of both CVD and depression. For example, studies of occupational groups have shown markedly different rates of CVD and depression that are too large to be explained by known risk factors alone, and it is generally inferred that chemical, physical and/or work organizational exposures must be involved. While of relatively recent origins, the term ''work organization'' has evolved to serve as a rubric that encompasses diverse workplace exposures (often called job stressors) such as psychological demands, limited job control, work role demands and shift-work. There is considerable evidence that such factors play a role in the etiology of both CVD and depression, but design and sample size limitations of existing studies make it difficult to establish a causal association and make specific public health recommendations.

This proposed study will examine the relationships between specific job stressors, CVD and depression. To overcome the limitations of previous studies, we are proposing a five-year prospective study with a population of 20,000 workers, half of them women. Workers will be identified through 20 large businesses sampled from the four geographic Census regions of the U.S. Different types of businesses will be sampled in order to incorporate diverse types of jobs and work. Specific job stressors, perceived non-work stressors and general risk factors for CVD and depression will be assessed. To ascertain exposures and outcomes, the study will rely on employee medical records, blood samples, and both self-reports and work-site assessments of job conditions. Several instruments to evaluate the work environment will be used, including the NIOSH Generic Job Stress Questionnaire, which assess a variety of job stressors, as well as other relevant aspects of the work environment.

This request is for three years of the five-year proposed data collection with a total of 57,721 burden hours, and an average annualized burden of 28,860 hours.

Data	Number of respondents	Number of responses/ respondent	Average burden/response (in hours)
Baseline Interview/Blood Collection Biometrics	21,993	1	75/60
Medical Records for Baseline	4,398	1	30/60
Employer Information	15	1	5
Follow-up Interview 1	17,594	1	30/60
Refusal Questionnaire	4,399	1	5/60
Medical Records for Follow-up 1	3,519	1	30/60
Follow-up Interview 2	14,995	1	30/60
Refusal Questionnaire	2,639	1	5/60
Medical Records for Follow-up 2	2,999	1	30/60
Follow-up Interview 3	12,712	1	30/60
Refusal Questionnaire	2,243	1	5/60
Medical Records for Follow-up 3	2,542	1	30/60

Dated: August 19, 2003.

Nancy E. Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0361]

Anti-counterfeit Drug Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on the agency's initiative against counterfeit drugs. Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist FDA. This action is intended to ensure that there is a venue for information and comments to be submitted to the agency regarding the anti-counterfeit initiative.

DATES: The agency encourages interested parties to submit information by November 30, 2003.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* All comments submitted to the public docket are public information and may be posted to FDA's Web site (*http://www.fda.gov*) for public viewing. Please include the docket number listed in the heading of this document on all correspondence related to this docket.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *e-mail: pkendall@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous subpotent or superpotent ingredients. In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990's.

In an effort to protect against the rising occurrence of potentially unsafe counterfeit drugs reaching consumers, on July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks posed by counterfeit drugs. As part of this effort, FDA established an internal task force that will develop recommendations for steps FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain. Some of the areas that FDA's task force will explore include the following topics:

- *Technology:* Assess the extent to which new technologies can help assure the authenticity of drugs;
- *Regulatory/Legislative Issues:* Will evaluate potential regulatory and legislative changes that could be made to strengthen the nation's protections against counterfeiting;
- *Public Education:* Recommend ways to educate consumers and health providers on steps they can take to minimize risks associated with counterfeit drugs; will also educate consumers and health professionals about what to look for and what to do if they suspect they have received a counterfeit drug;
- *Industry and Health Professional Issues:* Identify actions industry and health professionals can take to prevent, detect, and respond to counterfeit drugs;

The task force has the following deliverables:

- Interim task force report to be released in September 2003. It will include draft recommendations on which interested persons may comment.
- Public meeting to be held in mid-October 2003. The meeting announcement will be published in a forthcoming **Federal Register** and will pose issues for discussion at the meeting.
- Final task force report to be released in January 2004.

Many individuals, vendors, trade and professional associations, consumer groups, and other stakeholders have offered to assist the agency and provide information that may be helpful in the agency's anti-counterfeit drug efforts. The agency requests that all persons or organizations that would like to provide such information submit it to this docket number.

FDA expects to place submissions it receives on this initiative in the public docket. Therefore, submitters should recognize that information submitted to this docket is public information and can be viewed and accessed by the general public.

Note that, as mentioned previously, the counterfeit task force expects to issue a report with draft recommendations for public comment in September of this year. In addition, the agency expects to hold a public meeting on these issues later this year as well. Comments on the draft report and the issues discussed at the public meeting will sought in future issues of the **Federal Register**.

Dated: August 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

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