policies for blood and blood products in response to the introduction of new safety measures.

Public comment will be solicited both days. Public comment will be limited to three minutes per speaker. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business April 10, 2000.

FOR FURTHER INFORMATION CONTACT: Stephen D. Nightingale, M.D., Executive Secretary, Advisory Committee on Blood Safety and Availability, Department of Health and Human Servcies, Office of Public Health and Safety, 200 Independence Avenue SW., Rm 736E, Washington, DC 20201. Phone (202) 690–5560 FAX (202) 690–7560 e-mail stephendnightingale@osophs.dhhs.gov.

Dated: March 9, 2000.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 00–6430 Filed 3–15–00; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–00–27]

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. Workplace Exacerbation of Asthma—NEW—The National Institute of Occupational Safety and Health (NIOSH)—Work-related asthma is the most common lung disease seen in occupational health clinics in the United States based on data from the Association of Occupational and Environmental Clinics for 1991–1996. Work-related asthma includes both new onset asthma initiated by workplace exposures and preexisting asthma exacerbated by workplace environments, because in both types of cases repeated exposure to asthmatic agents can lead to chronic pulmonary impairment. Also, the 1985 American Thoracic Society statement ''What Constitutes an Adverse Health Effect of Air Pollution'' identified exacerbation of asthma as one of the serious effects of environmental air pollution. While anecdotal evidence suggests that as many as one-half of work-related asthma patients treated in occupational medicine clinics had pre-existing asthma that was exacerbated by workplace conditions, there is little data from studies in the United States to support this claim.

This study will investigate the frequency, causes, and consequences of workplace exacerbation of asthma (WEA). Given the diversity of workplace agents and processes associated with asthma, a population-based, rather than industry-based, study is needed to ascertain the full extent of the problem. This will be achieved by surveying adults with asthma. The Specific Aims are: (1) To determine the frequency of workplace exacerbation of asthma. (2) To determine the circumstances at work associated with exacerbation of asthma. (3) To determine the social and economic costs associated with workplace exacerbation of asthma. (4) To determine the sensitivity and specificity of self-reported workplace exacerbation of asthma. (5) To determine whether workplace exacerbation of asthma contributes to progression of disease. The design is a prospective cohort study with a nested validation study. A questionnaire will be completed in the baseline study to address Specific Aims 1–3. Also, patient care records will be used to ascertain cost of asthma care for each participant (Specific Aim 3). A subset of employed subjects with and without workplace exacerbation will be requested to conduct serial spirometry, and the findings will serve as the ''gold standard'' to determine the sensitivity and specificity of a self-report of workplace exacerbation of asthma (Specific Aim 4). All subjects from the baseline study will be asked to complete a follow-up questionnaire approximately two years later to investigate whether workplace exacerbation at baseline predicts an increase in asthma severity (Specific Aim 5).

The data collected in this study will be used to further current understanding of the frequency of workplace-exacerbated asthma, the social and economic impacts of this problem, and the implication of a report of WEA for subsequent asthma severity. This information can be used to prioritize resources for addressing this problem. The data collected in this study will also identify which jobs and exposures are likely to exacerbate existing asthma, thus providing guidance on where to focus preventive efforts. The data collected in this study on the validity of a self-report of WEA will be useful to both clinicians and researchers who attempt to treat or study individuals with this problem.

Based on an average hourly wage of $15 among all occupational groups combined, the total cost to respondents is $37,500.

Respondents (adults with asthma)	Number of respondents	Number of responses/respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Baseline Study	800	1	0.5	400
Validation Study	240	1	7.5	1800
Follow-up Study	600	1	0.5	300
Total				2500

2. Jail STD Prevalence Monitoring System—New—National Center for HIV, STD, and TB Prevention (NCHSTP)—Proposes a 3-year clearance for data collection of the standardized record layout for the Jail STD Prevalence Monitoring System. This system consists of test data compiled for persons entering corrections facilities. The standard data elements were created in response to the need to systematically assess morbidity in persons entering corrections facilities who are at high risk for STDs and who often do not seek medical care in mainstream medical settings. Use of these standard data elements will improve surveillance of STDs by allowing for systematic assessment of a high risk population, taking advantage of already computerized data. States that compile data from corrections facilities are encouraged to participate in the system.

In most places, STD test results for persons in corrections facilities are computerized by the laboratory or by the health department. The burden of compiling data in the standardized format involves running a computer program to convert the data to the specified format. This involves an initial investment of time by a programmer but afterwards involves only running the program once a quarter (average of 3 hours/quarter). Therefore, the respondent burden is approximately 12 hours/year.

If a respondent does not already have computerized test results for persons in corrections facilities and must enter the data, the burden of data entry is approximately 1.5 minute per record, and on average respondent enter approximately 1250 records per quarter for a total burden of 1500 minutes/quarter (31 hours/quarter). During the next 3 years, we expect approximately 20 project areas per year to participate. Approximately 15 will have already computerized data for a burden of 180 hours (15×12hrs) per year and five will enter data for a burden of 620 hours (5×124 hrs) per year. The total burden to respondents is approximately 800 hours per year.

Total estimated cost to respondents is $13,800 per year. This is calculated by the above burden of 180 hours of computer programming time at $25/hr (180–0A$25=$4,500) plus 620 hours of data entry time at $15/hr (620–0A$15=$9,300) for a total of $13,800. The estimated cost to the Federal Government is $55,000 per year which includes the cost of staff time in providing technical assistance, managing and analyzing data, and preparing reports.

Respondents	Number of respondents	Number of responses/respondent	Average burden per response (in hrs.)	Total burden
State/local health departments.	Up to 65 STD project areas.	4 datasets/yr (approx 5000 total records).	3 hrs/dataset (if data entry needed, 31 hrs per dataset).	12 hrs/yr (if data entry needed, 124 hours/yr).
Total	.....	.....	.....	124

3. AIDS Prevention and Surveillance Project Reports, 0920–0208. The National Center for HIV, STD, and TB Prevention (NCHSTP)—proposes to continue data collection for the AIDS Prevention and Surveillance Project Reports, previously approved under OMB No. 0920–0208. This request is for a 3-year extension of clearance.

CDC funds cooperative agreements for 65 HIV Prevention Projects (50 states, 6 cities, 7 territories, Washington, D.C., and Puerto Rico). The cooperative agreements support counseling, testing, referral, and partner notification programs conducted by official public health agencies of states, territories, and localities (project areas). HIV counseling and testing in STD clinics, Women's Health Centers, Drug Treatment Centers, and other health agencies has been described as a primary prevention strategy of the national HIV Prevention Program. These project areas have increased HIV counseling and testing activities to specifically reach more minorities and women of child bearing age.

CDC is responsible for monitoring and evaluating HIV prevention activities conducted under the cooperative agreement. Counseling and testing programs are a major component of the HIV Prevention Program. Without data to measure the impact of counseling and testing programs, priorities cannot be assessed and redirected to prevent further spread of the virus in the general population. CDC needs information from all project areas on the number of at-risk persons tested and the number positive for HIV. The HIV Counseling and Testing Report Form provides a simple yet complete means to collect this information.

Respondents will be able to use either a manual or an electronic scan form. Seventeen respondents (project areas) will use the manual data collection tool. It takes approximately 2 hours to complete the form. The respondents will complete the form 4 times each year for a total burden of 8 hours per year per project area. Forty-eight (48) respondents (project areas) will use the scan form or client record format. It will take approximately 15 minutes for each project area to transfer data electronically on a quarterly basis for a total burden per project area of 1 hour per year. Therefore, the total burden hours for collecting this data will be 184 hours.

CDC will support costs to respondents for data collection and analysis in areas using the manual and scan form out of funds budgeted for these purposes. CDC will spend an estimated 650 hours entering, uploading, and analyzing the data. Using an estimated cost of $40 per hour, this cost would be $26,000 annually (650 hours ×$40). Using an estimated cost of $30.00 per hour, the total burden to the manual form respondent will be $240 annually (8 hours ×$30). ($4,080 total) Using an estimated cost of $30.00 per hour, the total burden to the scan form respondent will be $120 annually (4 hours ×$30) ($5,760 total).

The total cost to the Federal government will be approximately $26,000/year. The total cost to respondents will be approximately $9,840/year. The total burden hours are expected to be 184 burden hours per year.

Respondents	Number of respondents	Number of responses per respondent	Average burden response/ (in hrs.)	Total burden (in hrs.)
Manual form project areas	17	4	2	136
Scan form project areas	48	4	.25	48
Total	65			184

Dated: March 9, 2000.

Charles Gollmar,

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

[FR Doc. 00–6486 Filed 3–15–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0222]

Decision in Washington Legal Foundation v. Henney

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: In the **Federal Register** of August 12, 1999 (64 FR 44025), the Food and Drug Administration (FDA) published in its entirety an order entitled ''Final Amended Order Granting Summary Judgment and Permanent Injunction.'' The order was entered by the United States District Court for the District of Columbia in *Washington Legal Foundation* v. *Henney*, 56 F. Supp. 2d 81 (1999). The Court of Appeals subsequently vacated the district court decision and injunction (and earlier decisions and injunctions) insofar as they declared unconstitutional (1) Statutory provisions concerning the dissemination by manufacturers of certain written materials concerning new uses of approved products (21 U.S.C. 360aaa *et seq.*), and (2) an FDA guidance document concerning certain industry-supported scientific and educational activities known generally as industry-supported continuing medical education or ''CME.'' *Washington Legal Foundation* v. *Henney*, No. 99–5304, 2000 WL 122099, slip op. (D.C. Cir. Feb. 11, 2000). Consequently, these statutory provisions now constitute a ''safe harbor'' for manufacturers that comply with them; the CME guidance document details how the agency intends to exercise its enforcement discretion. FDA, consistent with its longstanding interpretation of the laws it administers, may proceed, in the context of case-by-case enforcement, to determine from a manufacturer's written materials and activities how it intends that its products be used. The Court of Appeals also recognized that if the agency brings an enforcement action, a manufacturer may raise a First Amendment defense.

FOR FURTHER INFORMATION CONTACT:

Regarding biological products and devices regulated by the Center for Biologics Evaluation and Research: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6190.

Regarding human drug products: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828.

Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639.

SUPPLEMENTARY INFORMATION: The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), as amended, generally prohibits the manufacturer of a new drug or medical device [1] from distributing a product in interstate commerce for any intended use that FDA has not approved as safe and effective. The intended use or uses of a drug or device may be set forth in, among other things, its label or ''labeling,'' which includes written, printed, or graphic matter affixed to or ''accompanying'' the product. See 21 U.S.C. 321(m); 21 CFR 202.1(l)(2); see also 21 CFR 201.128, 801.4. The intended use or uses of a drug or device may also be determined from advertisements, promotional material, oral statements by the product's manufacturer or its representatives, and any other relevant source. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980); see also 21 CFR 201.128 and 801.4.

When FDA approves a drug or medical device, the agency approves the product for each use set out in the product's approved labeling. A use that FDA approves is thus sometimes referred to as an ''approved'' or ''labeled'' use. A use that does not appear in the labeling is not approved as safe and effective by FDA and is known as an ''unapproved'' or ''off-label'' use. In this notice, such a use is referred to as a ''new use.''

A central feature of the FDCA is that it generally prohibits interstate commerce in new drugs and devices for ''new uses.'' In particular, the statute provides that ''[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [21 U.S.C. § 355(b) or (j)] is effective with respect to such drug.'' 21 U.S.C. 355(a); see 21 U.S.C. 331(d). Such an application must identify the particular use or uses to which the new drug will be put, and an approval of such an application for interstate distribution can become effective only with respect to such use(s). See 21 U.S.C. 355(b), (d), (j). Thus, an approved new drug that is marketed for a ''new use'' becomes an unapproved new drug with respect to that use.

An approved new drug that is marketed for a ''new use'' is also ''misbranded'' under the FDCA, because the labeling of such a drug would not include ''adequate directions for use.'' 21 U.S.C. 352(f); see *United States* v. *Articles of Drug * * * Rucker Pharmacal Co.,* 625 F.2d 665, 673 (5th Cir. 1980). Similarly, a medical device that is distributed for a ''new use'' is ''adulterated,'' see 21 U.S.C. 351(f), and ''misbranded,'' see 21 U.S.C. 352(f). An adulterated or misbranded product is prohibited from distribution in interstate commerce (21 U.S.C. 331(a), (k)), as is a drug that is marketed for a ''new use'' (21 U.S.C. 331(d)).

An approved new drug that is marketed for a ''new use'' may be seized (because it is an unapproved new drug with respect to that use), as may an adulterated or misbranded new drug or device (21 U.S.C. 334), and the government may seek an injunction against, or criminal prosecution of,

[1] For purposes of this notice, the terms ''drug or medical device'' include biologic products regulated under section 351(a) of the Pubic Health Service Act.