representative data regarding high school students and tobacco. Moreover, the National Youth Tobacco Survey is the only source of such national data for middle school students (grades 6–8). The data have significant implications for policy and program development for school health programs nationwide.

To provide contextual data, in each participating school, the principal or another designated administrator will be asked to complete a questionnaire on the school's tobacco-related policies. The lead health teacher identified by the principal will be asked to complete a questionnaire on the school's tobacco-related programs and curricula.

The only cost to respondents is their time to complete the survey.

Respondents	Number of respondents	Number of responses per respondent	Average burden per responses (in hrs.)	Total burden (in hrs.)
Students	24,500	1	45/60	18,375
School Administrator Arrangements	236	1	30/60	118
School Administrator Policy Survey	236	1	20/60	79
School Teacher Program Survey	236	1	20/60	79
Total				18,651

Dated: July 17, 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

[60Day–03–100]

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) 498–1210.

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. Send comments to Anne O'Connor, 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: Workplace Exacerbation of Asthma (0920–0495)—EXTENSION—National Institute of Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

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 pre-existing 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 are few data from studies in the United States to support this claim.

This study is investigating 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 of the study are: (1) To determine the frequency of WEA. (2) To determine the work circumstances associated with exacerbation of asthma. (3) To determine the social and economic costs associated with WEA. (4) To determine the sensitivity and specificity of self-reported WEA. (5) To determine whether WEA contributes to progression of disease. The design is a prospective cohort study with a nested validation study. The study consists of three parts: a Baseline Study addressing Specific Aims 1–3, a Validation Study addressing Specific Aim 4, and a Follow-up Study addressing Specific Aim 5.

To date, the Baseline Study telephone interviews have been completed with a total of 615 participants. Also, patient care records have been obtained in order to ascertain cost of care for asthma for each participant (Specific Aim 3). Currently, a subset of employed subjects with and without WEA are being enrolled in the Validation Study. All subjects from the Baseline Study will be asked to participate in the Follow-up study.

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 self-reporting 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. Collected data on the validity of self-reporting WEA will be useful to both clinicians and researchers who attempt to treat or study individuals with this problem.

There will be no costs to respondents.

Respondents (adults with asthma)	Number of respondents	Number of responses/ respondent	Average burden per response (in hours)	Total burden (in hours)
Validation Study	200	1	7.51	500
Follow-up Study	465	1	30/60	233
Total	665			1733

Dated: July 17, 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. 2003D–0319]

Draft Guidance for Industry and FDA Staff; Premarket Assessment of Pediatric Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Assessment of Pediatric Medical Devices.'' This draft guidance presents FDA's current thinking on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by October 22, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Premarket Assessment of Pediatric Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues contact: Joy Samuels-Reid, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287 ext. 177.

For biologics issues contact: Edward Tabor, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, was signed into law. Among other things, MDUFMA amends the Federal, Food, Drug, and Cosmetic Act (the act) by adding several new provisions concerning devices intended for pediatric use. MDUFMA requires FDA, within 270 days of enactment, to issue guidance on the safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products. This guidance, as well as a collateral guidance on procedures for ensuring appropriate pediatric expertise on FDA Advisory Panels, ''Pediatric Expertise for Advisory Panels'' (*http://www.fda.gov/cdrh/ode/guidance/1208.html*), will help the agency achieve the intent of the pediatric provisions of MDUFMA.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Premarket Assessment of Pediatric Medical Devices.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Premarket Assessment of Pediatric Medical Devices'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1220) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) . The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket