Dated: June 11, 2001.

Chuck Gollmar,

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

[FR Doc. 01–15357 Filed 6–15–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–32–01]

Agency Forms Undergoing Paperwork Reduction Act Review

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) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project: National Survey of STD Services Provided to U.S. College Students—New—The National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC) plans to conduct a survey of a sample of U.S. colleges asking about health services available to students with focus on sexually transmitted disease (STD) testing and management. The sample shall include a broad range of colleges including 2 and 4 year, public and private, and rural and urban colleges to determine under what conditions, for which STDs, and how colleges educate about STDs, conduct testing and provide partner management.

STDs have a large economic and health impact throughout the United States. Most college students are within the age range with the highest rates for STDs (15–24 year olds). *Chlamydia trachomatis* is the most frequently reported infectious disease in the United States with prevalence rates of 4% to 18% in 16–24 year old women. Infections with *Chlamydia trachomatis* can result in pelvic inflammatory disease and infertility. Many STDs increase the risk of HIV transmission and acquisition. Genital infections with herpes simplex virus, human papillomavirus, and *Trichomonas vaginalis* have been reported at increasing rates over the last 10 years.

This national survey will provide data that will broaden the scientific knowledge related to STD services and management available to students at U.S. colleges. The survey is intended to (a) describe health insurance policies of colleges; (b) describe preventive services such as health education and condom availability at colleges; (c) identify characteristics of student health centers including staffing, type of care, and number of students seen; (d) identify possible obstacles to accessing STD services; (e) describe which STDs are being tested for and what testing criteria are applied; and (f) describe current partner services including partner notification practices and use of partner-delivered therapy. The total response burden is estimated at 455 hours.

Respondents	Number of respondents	Number of response per respondent (in hours)	Average burden per response (in hours)
Health Service Manager	455	1	30/60
Chief Administrative Officer	455	1	30/60

Dated: June 11, 2001.

Chuck Gollmar,

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

[FR Doc. 01–15358 Filed 6–15–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State High Performance Bonus System (HPBS) Transmission File Layouts for HPBS Work Measures

OMB No. New Collection.

Description: The purpose of this collection is to obtain data upon which to base the computation for measuring State performance in meeting the legislative goals of TANF as specified in section 403(a)(4) of the Social Security Act and 45 CFR Part 270. Specifically, DHHS will use the data to award the portion of the bonus that rewards States for their success in moving TANF recipients from welfare to work. This information collection will replace Form ACF–200 in FY 2002 (Bonus Year 2002). States will not be required to submit this information unless they elect to compete on a work measure for the TANF High Performance Bonus awards.

Respondents: Respondents may include any of the 50 States, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State High Performance Bonus System (HPBS) Transmission File Layouts for HPBS Work Measures	54	2	16	1,728
Estimated Total Annual Burden Hours	.....	.....	.....	1,728

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 12, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–15202 Filed 6–15–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0238]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for the F-Spoon device, a manual compression device that allows a radiologist to press on the abdomen during a fluoroscopic procedure without exposing his or her hand to the x-ray beam. The device is classified as an accessory to the image-intensified fluoroscopic x-ray system. FDA intends to expand the exemption to other fluoroscopic compression devices such as other types of spoons and compression paddles. FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by July 18, 2001.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). In the **Federal Register** of November 3, 1998 (63 FR 59222), FDA published a final rule codifying these exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These