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

factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http:// frwebgate.access.gpo. gov/cgi-bin/ leaving.cgi? from=leavingFR.html&log= linklog&to=http:// www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (159) followed by the pound sign (#). Follow the remaining voice prompts to complete the request.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for a class II device: 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 (21 CFR 892.1650). FDA is expanding the generic type of device being considered for exemption to other fluoroscopic compression devices such as other types of spoons and compression paddles.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this petition by July 18, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 4, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–15198 Filed 6–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Notice on Increasing Income Levels Used To Identify a ''Low-Income'' Family and Announcement of New Annual ''Low-Income'' Levels for Various Health Professions and Nursing Programs Included in Titles VII and VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice provides the Department's response to comments on increasing low-income levels and announces the new ''low-income'' levels for various programs included in titles VII and VIII of the Public Health Service (PHS) Act, which use the U.S. Bureau of the Census ''low-income'' levels to determine eligibility for program participation. The Department periodically publishes in the **Federal Register** low-income levels used to determine eligibility for grants and cooperative agreements to institutions providing training for (1) disadvantaged individuals, (2) individuals from a disadvantaged background, or (3) individuals from ''low-income'' families.

SUPPLEMENTARY INFORMATION:

This notice announces the proposed increase in income levels intended for use in determining eligibility for participation in the following programs:

Advanced Education Nursing (section 811)
Allied Health Special Projects (section 755)
Basic Nurse Education and Practice (section 831)
Dental Public Health (section 768)
Faculty Loan Repayment and Minority Faculty Fellowship Program (section 738)
General and Pediatric Dentistry (section 747)
Health Administration Traineeships and Special Projects (section 769)
Health Careers Opportunity Program (section 739)
Loans to Disadvantaged Students (section 724)
Physician Assistant Training (section 747)
Primary Care Residency Training (section 747)
Public Health Traineeships (section 767)
Quentin N. Burdick Program for Rural Interdisciplinary Training (section 754)
Residency Training in Preventive Medicine (section 768)
Scholarships for Disadvantaged Students (section 737)
Public Health Training Centers (section 766)
Nursing Workforce Diversity (section 821)

These programs generally award grants to accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, chiropractic, public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

Response to Comments

The Department published a notice in the **Federal Register** on March 30, 2001 (66 FR 17433) requesting public comments on increasing income levels used to identify a ''low-income'' family for the purpose of providing training in the various health professions and nursing programs included in titles VII and VIII of the PHS Act. The Department received five letters. Each commenter supported the new formula that increases income levels used to identify a ''low-income'' family.

Low-Income Levels

The Secretary defines a ''low-income'' family for programs included in titles VII and VIII of the PHS Act as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. The Department's poverty guidelines are based on poverty thresholds published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index.

The Secretary annually adjusts the low-income levels based on the Department's poverty guidelines and makes them available to persons responsible for administering the applicable programs. The following income figures will be used for health professions and nursing grant applications requesting FY 2002 funding.