Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number for this program is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

The applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, and Native Hawaiian or other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exists that inclusion is inappropriate or not reasonable, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

Application Submission and Deadline

The original and two copies of the application, PHS Form 5161–1 (OMB Number 0937–0189), must be submitted to Ron Van Duyne, Grants Management Officer, Attention: Patrick A. Smith, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Room 321, Atlanta, Georgia 30305, on or before February 23, 1998.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable proof of timely mailing.)

2. *Late Applications:* Applications which do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications shall not be considered in the current competition for funding and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and telephone number and will need to refer to NCEH Announcement 98019. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to announcement number 98019 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Patrick Smith, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–13, Atlanta, Georgia 30305, telephone (404) 842–6803, Internet: phs3@cdc.gov.

Programmatic technical assistance may be obtained from Lawrence E. Posey, Health Studies Branch, Division of Environmental Health, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop F–46, Atlanta, Georgia 30333, telephone (770) 488–7350, Internet: lep1@cdc.gov.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report; Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report; Stock No. 017–001–00473–1) referenced in the **INTRODUCTION** may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Dated: January 14, 1998.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–1327 Filed 1–20–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0531]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by February 20, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Exemptions and Variances from the Performance Standard for Electrode Lead Wires and Patient Cables

FDA regulations in part 898 (21 CFR part 898) mandate a performance standard for electrode lead wires and patient cables. The purpose of the performance standard is to prevent electrocution from the use of unprotected electrode lead wires and patient cables with medical devices. To provide maximum flexibility in situations where the electrical accidents can be prevented in other ways, § 898.14 provides that any person subject to the performance standard may submit a petition under 21 CFR 10.30 requesting an exemption or variance from the standard. The petition must demonstrate why compliance with the standard is unnecessary or unfeasible and what alternate means will be used to protect the public health. FDA will use this information to determine whether granting an exemption is in the best interests of the public health. Allowing for exemptions and variances will provide for flexibility while assuring public health protection. Section 898.14 is stayed pending OMB clearance. FDA will announce the effective date of § 898.14 in the **Federal Register**. Anticipated respondents to this collection of information are medical device manufacturers and distributors, and health care facilities.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	50	1	50	10	500

[1] There are no capital costs or operating maintenance costs associated with this collection of information.

Dated: January 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1294 Filed 1–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0015]

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 list of class II (special controls) devices, subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the FDAMA). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the FDAMA.

DATES: Effective January 21, 1998. Comments on this notice should be submitted within 90 days of publication. The agency will review any comments submitted within the 90-day comment period and will consider whether the list of class II devices that are exempt from the premarket notification requirements should be modified.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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 (Pub. L. 94–295)), as amended by the the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 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 assure 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 which 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. Unless exempted from premarket notification requirements, persons may not market a new device, under section 510(k), unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II (section 513(I) of the act).

On November 21, 1997, the President signed into law the FDAMA. Section