

Headquarters, 200 Independence Avenue, SW, Room 5-35E, Washington, DC 20201

Centers for Disease Control and Prevention

CDC Employee Assistance Program Administrator, Personnel Management Office, 1600 Clifton Road, NE, Mail Stop K17, Atlanta, GA 30333

Southwest Complex

Employee Assistance Program Administrator, Program Support Center, 330 C Street, SW, Room 1036 Washington, DC 20201

Health Care Financing Administration

HCFA Employee Assistance Program Administrator, 7500 Security Boulevard, C2-15-05, Baltimore, MD 21244

National Institutes of Health

NIH Employee Assistance Program Administrator, Building 31, Room 1C02, 9000 Rockville Pike, Bethesda, MD 20892

Parklawn/Hyattsville Complex

Employee Assistance Program Team Leader, Office of the Secretary, ASMB, HHS EAP Headquarters, 200 Independence Avenue, SW, Room-35E, Washington, DC 20201

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Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Injury Prevention and Control (ACIPC).

Times and Dates: 2 p.m.-4 p.m., March 24, 1997. 8:30 a.m.-3:30 p.m., March 25, 1997.

Place: The Ritz-Carlton, Atlanta (Downtown), 181 Peachtree Street, NE, Atlanta, Georgia 30303.

Status: Closed: 2 p.m.-3 p.m., March 24, 1997, and 8:30-9 a.m., March 25, 1997; Open: 3 p.m.-4 p.m., March 24, 1997, and 9 a.m.-3:30 p.m., March 25, 1997.

Purpose: This committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee provides advice on the appropriate balance and mix of intramural and extramural research, including laboratory research, and provides guidance on intramural and extramural scientific program matters, both present and future, particularly from a long-range viewpoint. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee recommends areas of research to be supported by contracts and provides concept review of program proposals and announcements.

Matters to be Discussed: The meeting will convene in closed session from 2 p.m. to 3 p.m. on March 24, 1997. The purpose of this closed session is for the Science and Program Review Work Group to consider Injury Control Research Center grant applications recommended for further consideration by the CDC Injury Research Grant Review Committee. On March 25, 1997, from 8:30 a.m. to 9 a.m., the meeting will convene in closed session in order for the full Committee to vote on a funding recommendation. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c)(4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463. Following the closed session there will be discussions on future grant program announcements, ad hoc committee reports, and updates on further progress on standing Work Group issues. The Committee will also discuss (1) an update from the Director, National Center for Injury Prevention and Control (NCIPC); (2) Safe America: Advancing the Initiative; and (3) a report

from the Science and Program Review Work Group which will include reports on the motor vehicle programmatic review and poison control centers.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Mr. Thomas A. Blakeney, Acting Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, Georgia 30341-3724, telephone 770/488-1481.

Dated: March 4, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-5818 Filed 3-6-97; 8:45 am]

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Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Detailed Case Data Component (DCDC) of the National Child Abuse and Neglect Data System.

OMB No.: 0980-0256.

Description: The Detailed Case Data Component of the National Child Abuse and Neglect Data System compiles automated case-level data on child maltreatment investigated by State child protective services agencies. Data are collected on reports of abuse and neglect, characteristics of victims, risk factors associated with victims and their families, and the development of policies and programs relating the child abuse and neglect at the National, State and local levels.

Respondents: State, Local or Tribal Govt.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DCDC	56	1	110	6,160

Estimated Total Annual Burden Hours: 6,160.

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,

Division of Information Resource Management 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: March 3, 1997.

Bob Sargis,

Acting Reports Clearance Officer

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Food and Drug Administration

[Docket No. 97N-0022]

Agency Information Collection Activities: Proposed Collection; Reinstatements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the Federal Register concerning each collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements relating to the manufacture and distribution of hearing aid devices, reporting requirements for firms that provide electronic product samples to FDA for research and testing purposes, reporting requirements for firms that intend to export certain unapproved medical devices, and reporting and recordkeeping requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further process labeling or repackaging.

DATES: Submit written comments on the collection of information requirements by May 6, 1997.

ADDRESSES: Submit written comments on the collection of information requirements to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1479.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to the following collections of information, FDA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burdens of the proposed collections of information, including the validity of the methodologies and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burdens of the collections of information on respondents, including through the use of appropriate automated collection techniques, when appropriate, and other forms of information technology.

1. Hearing Aid Devices: Professional and Patient Package Labeling and Conditions for Sale—21 CFR 801.420 and 801.421 (OMB Control No. 0910-0171—Reinstatement)

Under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(e)), the Secretary of the Department of Health and Human Services (the Secretary) may, under certain conditions, require by regulation that a device be restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other prescribed conditions. Sections 801.420 and 801.421 (21 CFR 801.420 and 801.421) implement this authority for hearing aids, which are restricted devices. The regulations require that the manufacturer or distributor provide to the user data useful in selecting, fitting, and checking the performance of a hearing aid through distribution of a User

Instructional Brochure. The User Instructional Brochure must also contain technical data about the device, instructions for its use, maintenance, and care, a warning statement, a notice about the medical evaluation requirement, and a statement if the aid is rebuilt or used.

Hearing aid dispensers are required to provide the prospective user, before the sale of a hearing aid, with a copy of the User Instructional Brochure for the hearing aid model that has been, or may be, selected for the prospective user and to review the contents of the brochure with the buyer. In addition, upon request by an individual who is considering the purchase of a hearing aid, the dispenser is required to provide a copy of the User Instructional Brochure for that model hearing aid or the name and address or telephone number of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained. Under conditions of sale of hearing aid devices, manufacturers or distributors shall provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users and provide a copy of the User Instructional Brochure to any health care professional, user, or prospective users who requests a copy in writing. The regulations also require that the patient provide a written statement that he or she has undergone a medical evaluation within the previous 6 months before the hearing aid is dispensed, although informed adults may waive the medical evaluation requirement by signing a written statement. Finally, the regulation requires that the dispenser retain for 3 years copies of all physician statements or any waivers of medical evaluations.

The information obtained through this collection of information is used by FDA to ensure that hearing aids are sold and used in a way consistent with the public health.

The information contained in the User Instructional Brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser. The data is used by these health care professionals to evaluate the suitability of a hearing aid, to permit proper fitting of it, and to facilitate repairs. The data also permits the comparison of the performance characteristics of various hearing aids. Noncompliance could result in a substantial risk to the hearing impaired because the physician, audiologist, or dispenser would not have sufficient data to match the aid to the needs of the user.