

community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters To Be Discussed: Agenda items include: Presentations from the National Center for Environmental Health (NCEH) regarding current activities; the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies. Additional items include: the National Academy of Sciences review of the Fernald Dosimetry Reconstruction Project and an overview of the Fernald Medical Monitoring Program.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Steven A. Adams or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health, NCEH, CDC, 4770 Buford Highway, NE (F-35),

Atlanta, Georgia 30341-3724, telephone 770/488-7040, FAX 770/488-7044.

Dated: October 22, 1996.

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

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Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:
Title: Interim Application and Planning Document.

OMB No.: New Collection.

Description: This legislatively-mandated plan serves as the agreement between the grantee and the Federal government as to how child care funds from former Title IV-A Aid to Families with Dependent Children (AFDC) program will be operated under the new integrated Child Care and Development Fund. The plans provide assurances that the funds will be administered in conformance with legislative requirements, pertinent Federal regulations, and other applicable instructions or guidelines issued by ACF.

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
Interim Application and Planning Document (States)	51	1	60	1,020
Interim Application and Planning Document (Tribes)	226	1	20	4,520
<i>Estimated Total Annual Burden Hours</i>				5,540

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, S.W., Washington, D.C. 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: October 21, 1996.

Douglas J. Godesky,
Reports Clearance Officer.
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Food and Drug Administration

[Docket No. 96M-0381]

Cochlear Corp.; Premarket Approval of New Indication for Use for the Nucleus 22-Channel Cochlear Implant.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Cochlear Corp., Englewood, CO for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of a new indication for use for the Nucleus 22-Channel Cochlear Implant. After reviewing the recommendation of the Ear, Nose, and Throat Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 21, 1995, of the approval of the application.

DATES: Petitions for administrative review by November 27, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marilyn N. Flack, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

SUPPLEMENTARY INFORMATION: On August 8, 1992, Cochlear Corp., Englewood, CO 80112, submitted to CDRH a supplemental application for premarket approval of an expanded indication for use for the Nucleus 22-Channel Cochlear Implant. The device was originally approved in 1985 for use in adults who demonstrated postlinguistic, bilateral, sensorineural hearing loss, and obtained little or no benefit from conventional amplification. It was approved in 1990 for use in children who demonstrated bilateral, profound, sensorineural hearing loss, and obtained little or no benefit from conventional amplification or vibrotactile hearing aids. The expanded indication for use now includes patients, 18 years and older, who have bilateral, postlinguistic,