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).

[FR Doc. 96–27547 Filed 10–25–96; 8:45 am]

BILLING CODE 4163–18–M

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
Estimated Total Annual Burden Hours				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.

[FR Doc. 96–27523 Filed 10–25–96; 8:45 am]

BILLING CODE 4184–01–M

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,

sensorineural hearing impairment, and obtain limited benefit from appropriate binaural hearing aids. Limited benefit from amplification is defined by test scores of 30 percent or below in the best-aided (i.e., testing on left ear, right ear, and binaurally to determine communication ability obtained in that particular hearing-aided condition) listening condition on tape recorded tests of open set sentence recognition. These patients typically have low frequency residual hearing in the moderate to profound range and profound (greater than equal to 90 dBHL (decibels in hearing level)) hearing loss in the mid to high speech frequencies.

On April 20, 1995, the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On August 21, 1995, CDRH approved the supplemental application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 27, 1996 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 4, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–27613 Filed 10–25–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Veterinary Medicine Advisory Committee

Date, time, and place. November 20, 1996, 8:30 a.m., Best Western, Grand Ballroom, 1251 West Montgomery Ave., Rockville, MD.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; Richard E. Geyer, Center for Veterinary Medicine (HFV–244), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1764, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Veterinary Medicine Advisory Committee, code 12546. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before November 13, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will continue the discussion about the status of the sometribove Post-Approval Monitoring Program. FDA approved sometribove, a recombinant bovine somatotropin, on November 12, 1993 (58 FR 55946), and the product, Posilac®, began commercial distribution on February 4, 1994.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting