Analysis of Proposed Consent Order To Aid Public Comment (Filtration Manufacturing, Inc.)

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order from Filtration Manufacturing, Inc., a corporation (FMI), and Gary L. Savell (Savell), Horace R. Allen (Allen) and Brandon R. Clausen (Clausen). FMI manufactures and sells air filters for use in residential heating systems, under the brand name Allergy 2000, among others. The proposed consent order has been placed on the public record for sixty (60) days to receive the comments of interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The Commission's complaint charges that FMI, deceptively advertised that (1) use of the Allergy 2000 filter will substantially reduce the incidence of allergies caused by indoor allergens under household living conditions; (2) use of the Allergy 2000 will substantially reduce the amount of disease-causing germs in the air people breathe under household living conditions; (3) use of the Allergy 2000 will substantially reduce the incidence of disease caused by germs in the air people breathe under household living conditions; (4) people who use the Allergy 2000 in their homes will be healthier and have fewer illnesses than they would if they used a conventional filter; and, (5) the Allergy 2000 removes substantially all of the airborne contaminants, including allergens, from the air people breathe under the household living conditions. The complaint charges that FMI lacked substantiation for these claims. The complaint charges that these claims were made through advertisements and promotional materials and through use of the trade name ''Allergy 2000.''

In addition to the health-related claims listed above, the complaint also charges that FMI deceptively advertised that consumers would have lower utility bills if they replaced conventional filters with the Allergy 2000. The complaint charges that FMI lacked substantiation for this claim, too.

The complaint charges that Savell, Allen and Clausen formulated and controlled the affairs of FMI, including the acts and practices charged in the complaint.

The proposed order contains provisions designed to prevent misrepresentations related to these specific matters and others. Paragraph I of the proposed order prohibits FMI, Savell, Allen and Clausen (the respondents) from making any representation regarding the performance, health or other benefits, or efficacy of any air cleaning product (which is defined) unless they can substantiate the claims with competent and reliable evidence. If the representation states or implies a level of performance under household conditions, then the evidence that substantiates the representation must either be related to such conditions or must have been extrapolated to household conditions by generally accepted procedures.

Paragraph II prohibits the respondents from using the trade name Allergy 2000 or any other name that represents that the product will relieve allergy symptoms unless they can substantiate the representation.

Paragraphs III, IV, VI, and VII are compliance and reporting provisions that require the respondents to maintain for five (5) years the records on which they rely to substantiate any representation covered by the order, to provide copies of the order to certain employees of FMI, to notify the Commission in the event of changes in FMI that may affect compliance obligations arising out of the order, and to file a compliance report with the Commission within sixty (60) days after the order becomes final. Paragraph V requires Savell, Allen and Clausen to notify the Commission of any change in their business affiliation.

Paragraph VIII provides that the order will terminate automatically twenty years from the date it becomes final unless the Commission has brought an aciton in federal court alleging a violation of the order. In that case, the order will terminate twenty years from the date that the federal court action is filed.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

[FR Doc. 96–27575 Filed 10–25–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Fernald Health Effects Subcommittee.

Times and Dates:

9 a.m.–5 p.m., November 13, 1996
9 a.m.–5:05 p.m., November 14, 1996

Place: Eagle Conference Center, 2844 Mack Road, Fairfield, Ohio 45014, telephone 513/874–8850, FAX 513/874–8581.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. The purpose of this meeting is to provide a forum for community and labor interaction and serve as a vehicle for

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,