significance of the differences in these messages. Given the significance of the underlying problem, FDA intends to undertake an educational effort, including press releases and consumer pamphlets. The agency requests the cooperation and assistance of industry and other private groups in this effort. The agency also requests comments on additional ways to educate the consumer.

The guidance represented here reflects FDA's current thinking on safe handling labeling for foods that need refrigeration by the consumer. This document does not bind FDA and does not create or confer any rights, privileges, benefits, or immunities for or on any persons.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Recommendations of the National Advisory Committee on Microbiological Criteria for Foods for Refrigerated Foods Containing Cooked, Uncured Meat or Poultry Products that are Packaged for Extended Refrigerated Shelf Life and that are Ready-To-Eat or Prepared with Little or No Additional Heat Treatment, January 31, 1990.

2. Guidelines for the Development, Production, Distribution, and Handling of Refrigerated Foods, National Food Processors Association, 1989.

3. Letter from J. Corby, New York Department of Agriculture and Markets to A. Dell'Aria, Virginia Department of Agriculture, September 8, 1995.

4. Memorandum from A. Dell'Aria, AFDO, December 20, 1995.

5. Letter from P. Griffin and R. Tauxe, CDC to K. Wachsmuth, FDA, February 14, 1995.

Dated: February 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4364 Filed 2–21–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–38]

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

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Rural Health Clinics, 42 CFR 491.9 Subpart A; *Form No.:* HCF–AR–38; *Use:* This information is needed to determine if rural health clinics meet the requirements for approval for Medicare participation. *Frequency:* Other (Initial application for Medicare); *Affected Public:* Individuals or Households; Business or other for profit; Not for profit institutions; Farms; Federal Government; and State, Local or Tribal Government; *Number of Respondents:* 3,076; *Total Annual Hours:* 9,744.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, e-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 13, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–4374 Filed 2–21–97; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESS: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7057; fax 301/402–0220). A signed Confidential Disclosure Agreement (CDA) will be required to receive copies of the patent applications.

Chromosomal Markers and Diagnostic Tests For Manic-Depressive Illness

S Detera-Wadleigh (NIMH), E Gershon (NIMH), J Badner (NIMH), L Goldin (NIMH), W Berrettini (Thomas Jefferson University), T Yoshikawa (NIMH), A Sanders (NIMH), L Esterling (NIMH)

Serial No. 60/029,278 filed 28 Oct 96

Licensing Contact: Stephen Finley, 301/496–7735, ext. 215.

Bipolar disease, or manic-depressive illness, affects approximately 1% of the population and is generally controlled through medication. Not all patients respond similarly to a given medication. A medication that works well in one individual may be ineffective in another individual. It is unclear why this is, but it has been theorized that bipolar disease may involve multi-genes, possible on several chromosomes. It is not known if one genetic locus dominates over another, but if one does, then it may explain the variable

medication effectiveness. One genetic locus has been identified on chromosome 18 having allelic variations which may be used to determine if an individual has an increased susceptibility to bipolar disease. This method may be useful in determining if an individual has an increased susceptibility to bipolar disease, or ultimately, it may provide a means to predict which medication will provide the best treatment. (portfolio: Central Nervous System—Diagnostics, in vitro)

The Use of Functional N-Methyl-D-Aspartate Antagonists to Ameliorate or Prevent Aminoglycoside-induced Ototoxicity

A Basile and P Skolnick (NIDDK)
Serial No. 08/712,477 filed 11 Sep 96

Licensing Contact:: Stephen Finley, 301/496–7735, ext. 215.

Aminoglycoside (AGS) antibiotics are extremely effective at treating bacterial infections such as sepsis, endocarditis, and tuberculosis, but are currently used in only 3% of all clinical admissions in the United States because of their tendency to induce ototoxicity. Approximately 30–40% of all patients who receive an AGS antibiotic will develop measurable and usually permanent hearing loss. A guinea pig model was used to test whether N-Methyl-D-Aspartate (NMDA) antagonists could prevent or reduce the severity of the hearing loss when AGS antibiotics were administered. For example, the NMDA antagonists, dizocilpine and ifenprodil, were tested with the AGS antibiotics, neomycin and kanamycin, and were found to prevent or lessen the hearing loss in over 98% of the animals tested. Over 75% of the tested animals maintained normal hearing levels. It is believed that the use of this method will allow physicians to readily administer aminoglycoside antibiotics without the fear of causing permanent hearing loss in the patient. (portfolio: Internal Medicine—Therapeutics, other)

A Basal Cell Carcinoma Tumor Suppressor Gene

M Dean et al. (NCI)
Serial No. 60/017,906 filed 17 May 96

Licensing Contact: Ken Hemby, 301/496–7735 ext. 265.

Novel human nucleic acid sequences and polypeptides derived from the tumor suppressor, PTC or patched gene which have been mapped to human chromosome 9q22.3–q31, have been discovered for use in cancer diagnosis and therapy. Mutations of this gene are associated with Nevoid Basal Cell Carcinoma Syndrome (NBCCS) a disease associated with skin cancer and human developmental defects such as Gorlin Syndrome comprising skeletal defects, craniofacial and brain abnormalities. Methods of detection of PTC in a tissue sample have been found as well as recombinant cells, antibodies, and pharmacological compositions useful in treatment of the disease. Methods of diagnosis of and therapy for NBCCS have also been found.

The PTC gene is thought to encode a protein which selectively switches off growth factor production in certain cells by interaction with members of the family of proteins encoded by the ''hedgehog'' gene, which instructs cells during development and growth. NBCCS is the result of abnormal PTC gene products that encode non-functional or functionally reduced NBCCS polypeptides. This lack of function may be caused by insertions, deletions, point mutations, splicing errors, premature termination codons, missing initiators, etc. The tumors caused by NBCCS are slow growing tumors that rarely metastasize, but which can cause significant morbidity and occasional mortality from local invasion. (portfolios: Cancer—Diagnostics; Cancer—Therapeutics; Cancer—Research Materials)

Process for Detecting Alzheimer's Disease Using Cultured Cells

KK Sanford-Miffin, R Parshad, JH Robbins (NCI)
Serial No. 08/611,330 filed 08 Mar 96 (CIP of 08/225,825, CIP of 07/957,315)

Licensing Contact: Leopold J. Luberecki, Jr., 301/496–7735 ext. 223.

A novel process has been developed for distinguishing between clinically normal individuals and those who have Alzheimer's disease (AD), a form of senile dementia that affects millions of Americans. This invention should aid considerably in the diagnosis of sporadic AD before signs and symptoms become fully apparent and will make it possible in familiar AD to determine the presence or absence of AD gene(s) years before the patient becomes symptomatic. Previous studies of AD revealed that cells cultured from patients with familial or sporadic AD were hypersensitive to the lethal effects of ionizing radiation; however, none of these assays provided large enough differences between normal and AD cells to be useful in reliably distinguishing an AD patient from normal. The present invention provides an improved assay that demonstrates very large differences between AD cells and normal cells because it is based on the cytogenic response of an individual's cultured cells to fluorescent light in the presence and absence of a DNA repair inhibitor during the post-exposure period. This greater difference makes it possible to distinguish a single AD cell line (i.e., a cell line from one AD patient) from lines from most, if not all, normal people. The test is conducted on either skin fibroblasts or peripheral blood lymphocytes. (portfolio: Central Nervous System—Diagnostics, in vitro, other)

Methods and Compositions for Monitoring DNA Binding Molecules in Living Cells

H Htun and G Hager (NCI)
OTT Reference No. E-021-96/0 filed 08 Dec 95 and OTT Reference No. E-021-96/1 (CIP); foreign rights are available

Licensing Contact: Stephen Finley, 301/496–7735, ext. 215.

This technology is directed to methods of detecting the binding of fluorescently labeled compounds to DNA by a direct, real time, visual detection and to the characterization/screening of ligands to ligand-dependent DNA-binding proteins. Using cell lines harboring multiple copies of a defined transcriptional regulatory unit, visualization system and assay have been developed to determine the effect of ligand in promoting binding of ligand-dependent DNA binding proteins to nuclear targets, including to a define transcriptional regulatory DNA sequence. Quantitative and qualitative analyses show that when this technology is applied to study the effect of ligand, such as antagonist RU486 and agonist dexamethasone, on the glucocorticoid receptor, agonist ligand induces a nuclear accumulation of the receptor in a dose-dependent manner that is strickingly different from an antagonist ligand. Furthermore, by taking advantage of a unique cell line designated 3134, which contains 200 copies of a promotor region each containing 4 copies of a specific DNA-binding sequence for the receptor in a tandem array thereby producing 1600 copies of the DNA binding region, the agonist-induced binding of the receptor to this array can be observed in living cells. This cell line and the related methods may prove to be an important aid in monitoring steriod administration to patients through the direct measurement of steroid activity from a blood sample. This method is also applicable for high throughput visual (quantitative and qualitative) screening of ligands to orphan receptors either agonist or antagonist, determining the effective dosage levels of agonist/antagonists on a real time basis, and to identify modifying chemical or biological agents that alter DNA-binding specificity in living cells. (portfolios:

Internal Medicine—Diagnostics, anti-inflammatory; Internal Medicine—Diagnostics, imaging agents; Internal Medicine—Therapeutics)

Dated: February 12, 1997.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 97–4369 Filed 2–21–97; 8:45am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Program Project Review Meeting.

Date: March 17–19, 1997.

Time: 7:30 pm—March 17, 5:00 pm—March 18, 8:00 am—March 19.

Place: Best Western, 4630 Lindell Boulevard, St. Louis, Missouri 63108.

Contact Person: Mary Bell, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 611A, 6130 Executive Boulevard, MSC 7410, Bethesda, MD 20892–7405, Telephone: 301/496–7978.

Purpose/Agenda: To evaluate and review grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552(c)(6), Title 5 U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: February 18, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4478 Filed 2–21–97; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of General Medical Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of General Medical Sciences Review Committee meeting:

Committee Name: Minority Biomedical Research Support Review Subcommittee.

Date: March 27–28, 1997.

Time of Meeting: 8:30 a.m.–5:00 p.m.

Open Session: 8:30 a.m.–9:30 a.m.—March 27.

Agenda: Special reports related to committee activities.

Closed Session: 9:30 a.m.–5:00 p.m.—March 27, 8:30 a.m.–5:00 p.m.—March 28.

Place: National Institutes of Health, Building 31—Conference Room 8, Bethesda, MD 20892.

Contact Person: Michael A. Sesma, Ph.D., Scientific Review Administrator, NIGMS, 45 Center Drive, Room 1AS–19, Bethesda, MD 20892–6200, 301–594–2048.

Purpose: To review institutional research training grant applications.

The meeting will be open to the public as indicated above, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sing language interpretation or other reasonable accommodations, should inform the Contact Person listed above in advance of the meeting.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6). Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375. Minority Biomedical Research Support [MBRS])

Dated: February 18, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4479 Filed 2–21–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: E–CC Couplind: Signaling Between Calcium Channels.

Date: March 18, 1997.

Time: 8:00 a.m.–adjournment.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Contact Person: Melvin H. Gottlieb, Ph.D., Natcher Building, 45 Center Drive, Rm 5AS–25U, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.

Purpose/Agenda: To evaluate and review a research grant application.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussion of this application could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. [93.846, Project Grants in Arthritis, Musculoskeletal and Skin Diseases Research], National Institutes of Health, HHS)

Dated: February 18, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4480 Filed 2–21–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

Name of Committee: Ad Hoc Smell, Taste and Touch and Chemosensory Disorders Subcommittee of the National Deafness and Other Communication Disorders Advisory Council.

Date: April 2, 1997.

Time: 1–4 pm.

Place: National Institutes of Health, Building 31C, Conference Room 9, 9000 Rockville Pike, Bethesda, MD 20892, (telephone conference call).

Contact Person: Mr. Baldwin Wong, Program Analyst, NIDCD/PPHRB, 31 Center Drive, MSC 2320, Room 3C–31, Bethesda, MD 20892–2320, (301) 496–7243.

Purpose: To discuss changes in the scientific field of smell, taste and touch and chemosensory disorders since the Research Plan was written, compare the research portfolio of the Institute with the priorities in the Research Plan to determine areas of emphasis and levels of activity, and identify gaps and suggest new initiatives in preparation for the updating of the smell, taste and touch and chemosensory disorders section of the Research Plan.

Attendance by the public will be limited to the space available. A summary of the Subcommittee's meeting and a roster of members may be obtained from Mr. Wong, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Wong in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173, Biological Research