ADDRESSES: *The Meeting:* The meeting will be held at the Centers for Medicare & Medicaid Services (CMS) headquarters, Multipurpose Room, 7500 Security Blvd, Baltimore, MD 21244.

Presentations and Comments: Submit formal presentations and written comments to Janet A. Anderson, Executive Secretary; Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.hcfa.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the CMS Medicare Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Janet A. Anderson, Executive Secretary, (410) 786–2700.

SUPPLEMENTARY INFORMATION: On August 13, 1999, we published a notice in the **Federal Register** (64 FR 44231) to describe the Medicare Coverage Advisory Committee (Committee), which provides advice and recommendations to us about clinical issues. This notice announces the following public meeting of the Committee.

Current Panel Members

Harold C. Sox, MD; Robert H. Brook, MD, ScD; Daisy Alford-Smith, PhD; Wade Aubry, MD; Linda Bergthold, PhD; Ronald M. Davis, MD; John H. Ferguson, MD; Leslie P. Francis, JD, PhD; Alan M. Garber, MD, PhD; Thomas V. Holohan, MA, MD, FACP; Joe W. Johnson, DC; Michael D. Maves, MD, MBA; Barbara McNeil, MD, PhD; Robert L. Murray, PhD; Frank Papatheofanis, MD, PhD; Randel E. Richner, MPH.

Meeting Topic

The Committee will act on the recommendation of the Diagnostic Imaging panel regarding FDG Positron Emission Tomography (PET) imaging for breast cancer diagnosis and staging, and the recommendation of the Drugs, Biologics and Therapeutics panel regarding use of levocarntine in End Stage Renal Disease (ESRD) patients.

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 90 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make a formal presentation you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section of this notice. In addition, the Executive Secretary must receive, by the Deadline for Presentations and Comments date listed in the **DATES** section of this notice, the names and addresses of proposed participants; a brief statement of the general nature of the evidence or arguments you wish to present; and a written copy of your presentation. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 5, 2001.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 01–23325 Filed 9–18–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Methodology for Determining If an Increase in a State's Child Poverty Rate Is the Result of TANF.

OMB No. 0970–0186.

Description: In accordance with Section 413(i) of the Social Security Act and 45 CFR part 284, DHHS intends to extend the following information collection requirements for instances when Census Bureau data show that a State's child poverty rate increased by 5% or more from 1 year to the next: (1) Optional submission of data on child poverty from an independent source; (2) if the increase in the State's child poverty rate is still determined to be 5% or more, an assessment of the impact of the TANF program(s) in the State on the child poverty rate; and (3) if DHHS determines from the assessment and other information that the child poverty rate in the State increased as a result of the TANF program(s) in the State, a corrective action plan.

Respondents: The respondents are the 50 States and the District of Columbia; and when reliable Census Bureau data become available for the Territories, additional respondents will be Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Optional Submission of Data on Child Poverty from an Independent Source	54	1	8	432
Assessment of the Impact of TANF on the Increase in Child Poverty	54	1	120	6480
Corrective Action Plan	54	1	160	8640
Estimated Total Annual Burden Hours				15552

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, 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 and other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 13, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–23326 Filed 9–18–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

PDA/FDA Viral Clearance Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Parenteral Drug Association (PDA)/FDA Viral Clearance Forum.'' The topic to be discussed is viral clearance for biologics.

Date and Time: The public workshop will be held on October 1, 2001, from 8 a.m. to 4:30 p.m., October 2, 2001, from 8:30 a.m. to 4:30 p.m., and October 3, 2001, from 8:30 a.m. to 3 p.m.

Location: The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD.

Contact:

For information regarding this notice: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944, e-mail: gearyn@cber.fda.gov.

For information regarding the public workshop: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3841, FAX 301–827–3843, e-mail: Whelan@cber.fda.gov, or Leslie Zeck, PDA, Inc., 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301–986–0293, FAX 301–986–0296, e-mail: zeck@pda.org.

If you need special accommodations due to a disability, please contact Leslie Zeck (address above) at least 7 days in advance.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax number), and registration fee to PDA, Inc., P.O. Box 79465, Baltimore, MD 21279–3465 by Monday, September 24, 2001. You may also register with PDA, Inc., by phone at 301–986–0293 or fax at 301–986–0296 with your credit card.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. You may obtain registration forms from PDA, Inc., (address above) or from the FDA Internet at http://www.fda.gov/cber/meetings.htm.

SUPPLEMENTARY INFORMATION: The public workshop is being cosponsored by FDA, CBER, and PDA, Inc. The goals of the public workshop are to discuss: (1) Current and new viral removal technologies; (2) issues related to the reuse of chromatographic columns with an emphasis on viral clearance requirements; (3) current opinions on the need to standardize quality attributes of viral preparations used as controls in spiking and infectivity assays; (4) current methods used to standardize or validate traditional infectivity assays; (5) implementation and acceptability of polymerase chain reaction (PCR), PCR enhanced reverse transcriptase, and real-time PCR-based viral assays, standardization and validation of these new assays, and (6) the potential of and issues related to bracket/matrix studies defining generic virus inactivation conditions. FDA expects that participation in this workshop will provide manufacturers a regulatory perspective on viral clearance and facilitate product development and approval.

Dated: September 10, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23264 Filed 9–18–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: 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 companies and may also be available for licensing.

ADDRESSES: 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 will be required to receive copies of the patent applications.

Batrachotoxins as Unique Activators of Sodium Channels

John W. Daly (NIDDK)
DHHS Reference No. E–237–01/0
Licensing Contact: Pradeep Ghosh; 301–496–7736 ext. 211; e-mail: *ghoshp@od.nih.gov.*

Natural products provide a wide range of biologically active agents, many of which have unique pharmacological activity and therapeutic potential. The present invention relates to the identification and characterization of two alkaloids, namely, ''batrachotoxin'' and ''homobatrachotoxin,'' isolated from extracts of amphibian skin. Biologically, both these agents are potent activators of sodium channels. The sodium channels are primarily expressed in peripheral nerve cells in pain pathways, where they regulate cellular excitability. Thus, these channels are drug targets for the treatment of pain and/or peripheral neuropathies. The use of batrachotoxin or homobatrachotoxin as research tools