

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.

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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.

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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

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DHHS Reference No. E-237-01/0
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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