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

is applicable to sodium channel studies related to the effects of local anesthetics, analgesics, antiarrythmics and anticonvulsants. Further, advancement of these studies and target validation present commercial opportunities to expand ion channel drug discovery into new therapeutic areas.

**Identification of a Cell-Surface Receptor for Papillomaviruses**

Douglas R. Lowy, Patricia Day and John T. Schiller (NCI)

DHHS Reference No. E–179–01/0, filed 1 May 2001

Licensing Contact: Sally Hu; 301/496–7056 ext. 265; e-mail: *hus@od.nih.gov*.

Human papillomavirus (HPV) are the central cause of genital warts and most cervical cancers, which kills about 200,000 women globally each year. 20 million Americans acquire genital HPV infections annually. Prophylactic and therapeutic vaccines under development will likely afford strain-specific protection, precluding comprehensive immunity. In contrast, the instant invention identifies the cellular receptor that may be broadly utilized by papillomaviruses to gain entry into the cells. It further teaches developing molecular decoys for the virus to bind to, thereby preventing infection. The cell surface exposed domain of the receptor is soluble, biologically stable and is therefore suited for different delivery strategies including topical application. It may also be used for screening potential anti-HPV compounds. It can be produced by genetic engineering methods and may therefore lend itself to production in large amounts at a reasonable cost.

**Secretion of Native Recombinant Lysosomal Enzymes by Liver**

Dr. Nina Raben et al. (NIAMS)

DHHS Reference No. E–067–01/0 filed 09 Apr 2001

Licensing Contact: Marlene Shinn; 301–496–7056 ext. 285; e-mail: *shinnm@od.nih.gov*.

Glycogen storage disease type II (GSDII) is an autosomal recessive disorder caused by the deficiency of acid alpha-glucosidase (GAA), a glycogen-degrading lysosomal enzyme. This deficiency results in generalized deposition of lysosomal glycogen in almost all tissues of the body and can ultimately lead to cardiac failure before the age of two years. Current treatment for the disease includes repairing the deficiency by injecting recombinant protein into the patient made from either cultured Chinese Hamster Ovary (CHO) cells or secreted in the milk from rabbits that bear the transgene for the protein under a milk-specific promoter. Both recombinant proteins produced are extremely inefficient in their uptake into and function in targeted tissues.

The NIH announces a new technology that relates to the use of hepatocytes whether in culture or in vivo for the production of human GAA. The hepatocytes produce appropriate post-translational modification of the enzyme in liver cells by proper glycosylation, thereby producing a superior enzyme capable of being easily taken up and localized intracellularly in the target tissue. Once there, the enzyme digests glycogen present in lysosomes.

**High-Volume On-Line Spectroscopic Composition Testing of Manufactured Pharmaceutical Dosage Units**

E. Neil Lewis, David J. Strachen, Linda H. Kidder (NIDDK)

DHHS Reference No. E–249–99/1 filed 14 Jul 1999

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: *berkleyd@od.nih.gov*.

The invention is a pharmaceutical dosage unit manufacturing process control system that uses continuous spectral imaging to test the actual composition of pharmaceutical dosages even in packaged drugs. The system can screen for errors in coloring of ingredients, for contamination or breakdown that occurs independent of coloring and for other types of errors that might not otherwise be detected. The system can perform composition measurements through the end-user package walls to detect contamination or damage that occurs during packaging. The invention performs composition analysis by comparing spectral information with libraries of known spectral signatures, allowing small concentrations of potentially dangerous contaminants to be detected. Relative quantities of ingredients can be directly measured, such that a change in the ratio of these ingredients can be detected.

Dated: September 7, 2001.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 01–23295 Filed 9–18–01; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### State-of-the-Science Conference on Endoscopic Retrograde; Cholangiopancreatography (ERCP) for Diagnosis and Therapy

Notice is hereby given of the National Institutes of Health (NIH) State-of-the-Science Conference on ''Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy,'' which will be held January 14–16, 2002, in the NIH's Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference begins at 8:30 am on January 14 and 15, at 9 am on January 16, and is open to the public.

ERCP is a procedure physicians use to diagnose and treat problems in the liver, gallbladder, bile ducts, and pancreas. It combines the use of X-rays and an endoscope, a long, flexible, lighted tube. ERCP first came into use about 30 years ago and has been applied to the diagnosis and management of a variety of gastrointestinal disorders. However, the value of ERCP relative to other means for diagnosing and treating these diseases has not been firmly established.

The purpose of the conference is to examine the current state of knowledge regarding the use of ERCP for diagnosis and therapy so that health care providers and the general public can make informed decisions about this important public health issue.

During the first day-and-a-half of the conference, experts will present the latest ERCP research findings to an independent non-Federal panel. After weighing all of the scientific evidence, the panel will draft a statement that will address the following key questions:

- What is the role of ERCP in gallstone disease?
- What is the role of ERCP in pancreatic and biliary malignancy?
- What is the role of ERCP in pancreatitis?
- What is the role of ERCP in abdominal pain of possible pancreatic or biliary origin?
- What are the factors determining adverse events or success?
- What future research directions are needed?

On the final day of the conference, the panel's draft statement will be read in public, at which time members of the public are invited to offer comments on the draft.

The primary sponsors of this meeting are the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the NIH Office of Medical