

Licensing Contact: Peter A. Soukas, J.D.; 301-435-4646; soukasp@mail.nih.gov.

A Unique Infectious Hepatitis C Virus Clone, Strain HC-TN (genotype 1a)

Description of Invention: It is anticipated that this infectious clone of hepatitis C virus (HCV) strain HC-TN (genotype 1a) will be useful for the development of vaccines and antiviral drugs that target HCV, genotype 1a. The HC-TN strain is unique because it has been shown to cause fulminant hepatitis. To date, only one other HCV strain, JFH1 (genotype 1b), has been isolated that is known to cause fulminant hepatitis. Additionally, little is known about the etiology of fulminant hepatitis C disease. Therefore, the HC-TN strain may be useful as a tool for studying the etiology of fulminant hepatitis. This invention includes the infectious clone, nucleotide sequences of the clone, and polypeptides encoded by the HC-TN clone. Methods are included for producing attenuated HCV, and for screening therapeutics against HCV and developing vaccines and diagnostics.

Apparently, no companies or other laboratories have this HC-TN strain. The availability of the pHC-TN clone will be highly useful to pharmaceutical companies since no further research is required for its commercialization into, e.g., assays for testing antiviral compounds targeting HCV.

Applications:

- Production of attenuated viruses and polypeptides.
- HCV vaccines, diagnostics, therapeutics and screening tool for anti-HCV compounds.

Advantages: There is no universally effective therapy against HCV infection. This invention enables development of vaccines, diagnostics and therapeutics that are specific for the HC-TN strain or HCV genotype 1a.

Development Status: The technology is currently in the preclinical stage of development.

Market: More than 80% of the HCV infections in North and South America, Europe, Russia, China, Japan and Australia are genotype 1. The instant technology may be transferred through biological materials licenses for territories in which no patent rights exist.

Inventors: Jens Bukh, Robert H. Purcell, Suzanne U. Emerson, Akito Sakai, Patrizia Farci (NIAID).

Publication: A Sakai et al. In vivo study of the HC-TN strain of hepatitis C virus recovered from a patient with fulminant hepatitis: RNA transcripts of a molecular clone (pHC-TN) are

infectious in chimpanzees but not in Huh7.5 cells. *J Virol.* 2007 July;81(13):7208-7219.

Patent Status: U.S. Patent Application No. 12/061,504 filed 02 April 2008 (HHS Reference No. E-249-2007/0-US-01); No foreign rights available.

Licensing Status: Available for licensing.

Licensing Contact: RC Tang, JD, LLM; 301-435-5031; tangrc@mail.nih.gov.

Dated: July 13, 2009.

Richard U. Rodriguez,

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

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

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

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel. Formative Children's Center Review 2.

Date: July 24, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P. O. Box 12233, MD EC-30, Research Triangle Park, NC 27709. (919) 541-1307. malone@niehs.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from

Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 14, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-17303 Filed 7-21-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Time and Date: 11 a.m.–12 p.m., July 23, 2009.

Place: The teleconference call will originate at the CDC.

Status: Open to the public. Teleconference access limited only by availability of telephone ports. To participate in the teleconference please dial 1 (800) 779-6036 and enter conference code 6417394.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and the Director, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), regarding: (1) The practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: The agenda will include a follow up discussion of CDC's *Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Novel Influenza A (H1N1) Virus Infection in a Healthcare Setting.*

Agenda items are subject to change as priorities dictate. This notice is being published less than 15 days prior to the meeting due to the public health emergency declared on April 26, 2009. There is a critical need for this committee to deliberate and discuss urgent matters related to the H1N1 virus, and be actively engaged in the national preparedness and response efforts as dictated by circumstances and events.

Contact Person For More Information:
Wendy Vance, HICPAC, Division of
Healthcare Quality Promotion, NCPDCID,
CDC, 1600 Clifton Road, NE., Mailstop D-10,
Atlanta, Georgia 30333 Telephone (404) 639-
2891 or *HICPAC@cdc.gov*.

The Director, Management Analysis and
Services Office, has been delegated the
authority to sign **Federal Register** notices
pertaining to announcements of meetings and
other committee management activities, for
both CDC and the Agency for Toxic
Substances and Disease Registry.

Dated: July 17, 2009.

Elaine L. Baker,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention (CDC).*

[FR Doc. E9-17514 Filed 7-21-09; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0302]

Withdrawal of Approval of New Animal Drug Applications; Ketamine; S- Methoprene; Nitazoxanide

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is withdrawing
approval of two new animal drug
applications (NADAs) and an
abbreviated new animal drug
application (ANADA) listed in table 1 of
this document. In a final rule published

elsewhere in this issue of the **Federal
Register**, FDA is amending the animal
drug regulations to remove portions
reflecting approval of these NADAs and
ANADA.

DATES: Withdrawal of approval is
effective August 3, 2009.

FOR FURTHER INFORMATION CONTACT: John
Bartkowiak, Center for Veterinary
Medicine (HFV-212), Food and Drug
Administration, 7519 Standish Pl.,
Rockville, MD 20855, 240-276-9079, e-
mail: *john.bartkowiak@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The
following sponsors have requested that
FDA withdraw approval of the two
NADAs and ANADA listed in table 1 of
this document because the products are
no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA/ANADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Wellmark International, 1501 East Woodfield Rd., suite 200, West Schaumburg, IL 60173	NADA 141-162 Zodiac Fleatrol Flea Caps (S-methoprene)	520.1390 (011536)
IDEXX Pharmaceuticals, Inc., 7009 Albert Pick Rd., Greensboro, NC 27409	NADA 141-178 NAVIGATOR Paste (nitazoxanide)	520.1498 (065274)
Abbott Laboratories, North Chicago, IL 60064	ANADA 200-279 KETAFLO Injection (ketamine HCl, USP)	522.1222a (000074)

Therefore, under authority delegated
to the Commissioner of Food and Drugs
and redelegated to the Center for
Veterinary Medicine, and in accordance
with § 514.116 *Notice of withdrawal of
approval of application* (21 CFR
514.116), notice is given that approval
of NADAs 141-162 and 141-178, and
ANADA 200-279, and all supplements
and amendments thereto, are hereby
withdrawn, effective August 3, 2009.

In a final rule published elsewhere in
this issue of the **Federal Register**, FDA
is amending the animal drug regulations
to reflect the withdrawal of approval of
these NADAs.

Dated: July 14, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-17408 Filed 7-21-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2009-0001]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency
Management Agency, DHS.

ACTION: Notice; 60-day notice and
request for comments; revision of a
currently approved information
collection; OMB No. 1660-0095; No
Form.

SUMMARY: The Federal Emergency
Management Agency, as part of its
continuing effort to reduce paperwork
and respondent burden, invites the
general public and other Federal
agencies to take this opportunity to
comment on a proposed revision of a
currently approved information
collection. In accordance with the
Paperwork Reduction Act of 1995, this
Notice seeks comments concerning the
process for the appeal of decisions of
flood insurance claims issued through
the National Flood Insurance Program

(NFIP). The appeal process establishes a
formal mechanism to allow
policyholders to appeal the decisions of
any insurance agent, adjuster, insurance
company, or any FEMA employee or
contractor, in cases or unsatisfactory
decisions on claims, proof of loss, and
loss estimates.

DATES: Comments must be submitted on
or before September 21, 2009.

ADDRESSES: To avoid duplicate
submissions to the docket, please use
only one of the following means to
submit comments:

(1) *Online.* Submit comments at
http://www.regulations.gov under
docket ID FEMA-2009-0001. Follow the
instructions for submitting comments.

(2) *Mail.* Submit written comments to
Office of Chief Counsel, Regulation and
Policy Team, DHS/FEMA, 500 C Street,
SW., Room 835, Washington, DC 20472-
3100.

(3) *Facsimile.* Submit comments to
(703) 483-2999.

(4) *E-mail.* Submit comments to
FEMA-POLICY@dhs.gov. Include docket
ID FEMA-2009-0001 in the subject line.

All submissions received must
include the agency name and docket ID.
Regardless of the method used for
submitting comments or material, all
submissions will be posted, without