

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Consensus Development Conference: Management of Hepatitis B; Notice

Notice is hereby given of the National Institutes of Health (NIH) "NIH Consensus Development Conference: Management of Hepatitis B" to be held October 20–22, 2008, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on October 20 and 21, and at 9 a.m. on October 22, and will be open to the public.

Hepatitis B is a major cause of liver disease worldwide, ranking as a substantial cause of cirrhosis and liver cancer. In the United States, about 1.25 million people are chronically infected with the virus, resulting in 3,000 to 5,000 deaths each year. However, this condition occurs more frequently in high risk groups, including Asian Americans, emigrants from areas of the world where hepatitis B is common (China, Korea, Southeast Asia, the Indian Subcontinent, Africa, and Micronesia), men who have sex with men, injection drug users, and recipients of blood and blood products before screening procedures with enhanced sensitivity were implemented in 1986. Since routine hepatitis B vaccination of U.S. children began in 1991, new cases of acute hepatitis B among children and adolescents have dropped by more than 95 percent—and by 75 percent across all age groups. In nonprotected individuals, transmission can result from exposure to infectious blood or body fluids containing blood. A major impediment to diagnosis is that many infected individuals are either asymptomatic or experience only nonspecific symptoms of disease, such as fatigue or muscle ache.

For approximately 90 percent of adults, acute infection with the hepatitis B virus is resolved by the body's immune system and does not cause long-term problems. The transition from acute to chronic infection appears to occur when the immune system does not effectively destroy and clear virus-infected cells. This leads to high blood levels of both hepatitis B DNA and antigens, as well as antibodies produced by the body in an attempt to combat the infection. The natural history of the disease is not well understood, however, which makes management of this complex disease challenging.

Many factors can influence treatment decisions for an individual patient, including age, ALT (alanine aminotransferase, a liver enzyme) level, viral load, liver biopsy results, and the presence of a co-infecting virus (i.e., HIV). Treatment decisions require in-depth analysis of multiple blood test results, which are typically repeated at regular intervals to monitor the disease course. There are currently six approved therapeutic agents: interferon-alpha, lamivudine, adefovir dipivoxil, entecavir, pegylated interferon, and telbivudine, which are often used in combination. Generally, these drugs act to decrease the risk of liver damage from hepatitis B by slowing or stopping the replication of the virus.

Questions remain as to which groups of patients benefit from therapy and at which point in the course of their disease. Specific recommendations for hepatitis B therapy are limited by a lack of reliable long-term safety and efficacy information. This is a difficult decision for physicians and patients, as treatments are expensive and may have bothersome, if not harmful, effects on patients. Left untreated, however, chronic hepatitis B can lead to liver failure and other serious liver problems. To examine these important issues, the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Medical Applications of Research of the National Institutes of Health will convene a Consensus Development Conference from October 20 to 22, 2008, to assess the available scientific evidence related to the following questions:

- What is the current burden of hepatitis B?
- What is the natural history of hepatitis B?
- What are the benefits and risks of the current therapeutic options for hepatitis B?
- Which persons with hepatitis B should be treated?
- What measures are appropriate to monitor therapy and assess outcomes?
- What are the greatest needs and opportunities for future research on hepatitis B?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Wednesday, October 22, the panel will present a statement of its collective assessment of the evidence to answer

each of the questions above. The panel will also hold a press conference to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting are the NIH National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888-644-2667, or by sending e-mail to consensus@mail.nih.gov. American Institutes for Research's mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at <http://consensus.nih.gov>.

Please Note: The NIH has instituted security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the security measures at NIH, please visit the Web site at <http://www.nih.gov/about/visitorsecurity.htm>.

Dated: August 4, 2008.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

[FR Doc. E8-18656 Filed 8-12-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2008 Performance Review Board

The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2008 Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the NIH Performance Review Board,

which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members:

Ms. Colleen Barros (Chair)
 Dr. Norka Ruiz Bravo
 Mr. Gahan Breithaupt
 Dr. Michael Gottesman
 Ms. Robin Kawazoe
 Dr. Raynard Kington
 Dr. Michael Marron
 Dr. Ellen Stover

For further information about the NIH Performance Review Board, contact the Office of Human Resources, Workforce Relations Division, National Institutes of Health, Building 31, Room B3C07, Bethesda, Maryland 20892, telephone 301-402-9203 (not a toll-free number).

Dated: August 5, 2008.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2008-0263]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625-0011

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) requesting an extension of their approval for the following collection of information: 1625-0011, Applications for Private Aids to Navigation and for Class I Private Aids to Navigation on Artificial Islands/Fixed Structures. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before September 12, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2008-0263] to the Docket Management Facility (DMF) at the U.S. Department of Transportation

(DOT) or to OIRA. To avoid duplication, please submit your comments by only one of the following means:

(1) Electronic submission. (a) To Coast Guard docket at <http://www.regulation.gov>. (b) To OIRA by e-mail via: oira_submission@omb.eop.gov.

(2) Mail or Hand delivery. (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(3) Fax. (a) To DMF, 202-493-2251. (b) To OIRA at 202-395-6566. To ensure your comments are received in time, mark the fax to the attention of the Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://www.regulations.gov>.

A copy of the complete ICR is available through this docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from Commandant (CG-611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523 or fax 202-475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

The Coast Guard invites comments on whether this information collection request should be granted based on it being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collections; (2) the accuracy of the estimated burden of the collections; (3) ways to enhance the quality, utility, and clarity of information subject to the collections; and (4) ways to minimize the burden of

collections on respondents, including the use of automated collection techniques or other forms of information technology.

Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. Comments to Coast Guard must contain the docket number of this request, [USCG 2008-0263]. For your comments to OIRA to be considered, it is best if they are received on or before the September 12, 2008.

Public participation and request for comments: We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the paragraph on DOT's "Privacy Act Policy" below.

Submitting comments: If you submit a comment, please include the docket number [USCG-2008-0263], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, an e-mail address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission. You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them. The Coast Guard and OIRA will consider all comments and material received during the comment period.

Viewing comments and documents: Go to <http://www.regulations.gov> to view documents mentioned in this Notice as being available in the docket. Enter the docket number [USCG-2008-0263] in the Search box, and click, "Go>>." You may also visit the DMF in room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments