

Date: April 12, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Robert Wellner, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452. (301) 594-4721. [rw175w@nih.gov](mailto:rw175w@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 3, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-5019 Filed 3-9-10; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cellular and Developmental Neuroscience.

Date: March 24, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Deborah L. Lewis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301-408-9129, [lewisdeb@csr.nih.gov](mailto:lewisdeb@csr.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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 2, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-5018 Filed 3-9-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Bureau of Health Professions; All Advisory Committee Meeting; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Bureau of Health Professions All-Advisory Committee Meeting (AACM).

Dates and Times: April 21, 2010, 8 a.m.–5 p.m.

Place: Doubletree Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Telephone: 301-652-2000.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to provide a venue for the Bureau of Health Professions' (BHP) four advisory committees [the Council on Graduate Medical Education (COGME), the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD), the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL), and the National Advisory Council on Nurse Education and Practice (NACNEP)] to continue their joint work on interdisciplinary education and practice, and to also discuss and identify future opportunities for collaboration.

Agenda: The AACM agenda will include updates on Bureau and Departmental priorities, discussion of the joint work on interdisciplinary education and practice, and proposals for future Advisory Committee collaboration. Agenda items are subject to change as priorities dictate.

For Further Information Contact:

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information can contact the Bureau of Health Professions, Office of the Associate Administrator, 5600 Fishers Lane, room 9-05, Rockville, Maryland, 20857, telephone (301) 443-5794. Information can also be found at the following Web site: <http://bhpr.hrsa.gov/>.

Dated: March 2, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010-5006 Filed 3-9-10; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0107]

#### Expanded Access to Direct-Acting Antiviral Agents for the Treatment of Chronic Hepatitis C Infection in Patients With Unmet Medical Need; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the agency) is announcing a public hearing to obtain input on the scope and implementation of potential expanded access programs with direct-acting antiviral agents (DAAs) for the treatment of chronic hepatitis C (CHC) infection in patients with unmet medical need. This public hearing is being held to obtain comments from the public on eligibility criteria that should be used for patient enrollment in expanded access protocols involving DAAs and to elicit suggestions for designs of protocols for treatment investigational new drug applications (INDs) involving DAAs and other expanded access protocols. In addition, the agency would like public input on types of studies that should be conducted to obtain information on patients with unmet medical need including those with the greatest risk of progression of liver disease and/or the lowest predicted virologic response rates.

DATES: The public hearing will be held April 30, 2010, from 9 a.m. to 4 p.m. The meeting may be extended or may end early depending on the level of public participation. Submit written or electronic requests for oral presentations and comments by April 8, 2010 (see section III of this document for details). Written or electronic comments will be accepted after the hearing until June 25, 2010 (see section V of this document for details).

ADDRESSES: The public hearing will be held at the Hilton Hotel, 1750 Rockville Pike, Rockville, MD 20852. Additional information on parking and public transportation may be accessed at <http://>

[www1.hilton.com/en\\_US/hi/hotel/IADMRHF-Hilton-Washington-DC-Rockville-Hotel-Executive-Meeting-Ctr-Maryland/index.do](http://www1.hilton.com/en_US/hi/hotel/IADMRHF-Hilton-Washington-DC-Rockville-Hotel-Executive-Meeting-Ctr-Maryland/index.do). (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 45 days after the hearing (see section VI of this document).

**FOR FURTHER INFORMATION CONTACT:** Susie Dill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6183, Silver Spring, MD 20993-0002, 301-796-3437, FAX: 301-847-8753, e-mail: [AccessToDAA@fda.hhs.gov](mailto:AccessToDAA@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

**A. CHC**

In the United States, hepatitis C virus infection causes 20 percent of all cases of acute viral hepatitis and from 70 to 90 percent of all cases of hepatocellular carcinoma. An estimated 3.2 million Americans are chronically infected with hepatitis C virus. CHC currently is the leading cause in the United States for liver transplantation, and modeling suggests that without effective treatment interventions, significant increases in CHC-associated liver morbidity and/or mortality could result.

According to treatment guidelines set forth by the American Association for the Study of Liver Diseases, the current standard of care (SOC) for treatment of CHC is a pegylated interferon administered in combination with ribavirin (See Marc G. Ghany, et al., "Diagnosis, Management, and Treatment of Hepatitis C: An Update," *AASLD Practice Guidelines*, (2009), available at [http://www.aasld.org/practice\\_guidelines/Pages/SortablePracticeGuidelinesAlpha.aspx](http://www.aasld.org/practice_guidelines/Pages/SortablePracticeGuidelinesAlpha.aspx)). Overall, following SOC treatment, sustained virologic response (SVR) occurs in about 40 to 45 percent of patients with viral genotype 1, with lower SVR rates for blacks and human immunodeficiency virus (HIV) co-infected patients.

Pegylated interferons and ribavirin are difficult to tolerate and can cause significant adverse reactions that limit treatment in many patients or result in substantial morbidity. Therefore, new drugs are needed (and many are in development) to increase SVR rates when added to an SOC, potentially to shorten the duration of interferon-based regimens, or to replace components of SOC regimens in patients who cannot tolerate interferons or ribavirin. New drugs also are needed to construct regimens in patients with decompensated cirrhosis and in patients undergoing liver transplant. One option for these patients may be early access to these developing drug products through the "expanded access" regulatory scheme.

**B. Authority for Expanded Access**

FDA regulations provide for treatment INDs or other access protocols for patients with serious or immediately life-threatening illnesses who have unmet medical need. See the Expanded Access to Investigational Drugs for Treatment Use Final Rule (Expanded Access Rule) (74 FR 40900, August 13, 2009). Under these regulations, a treatment IND, which permits patients access to unapproved drug products under certain circumstances prior to final agency approval, is possible when the following criteria have been met:

- (1) The drug is being investigated in a controlled clinical trial under an IND designed to support a marketing application for the expanded access use, or all clinical trials of the drug have been completed;
- (2) The sponsor is actively pursuing marketing approval of the drug for the expanded access use with due diligence; and
- (3) There is sufficient clinical evidence of safety and effectiveness to support the treatment use (21 CFR 312.320(a)).

Alternatively, individual patient INDs and treatment access protocols for intermediate-sized populations are sometimes possible earlier in drug development (21 CFR 312.310) (IND use for treatment of individual patient by licensed physician); 21 CFR 312.315 (IND use for treatment of patient population smaller than that typical of treatment IND). Proposed use under each of these three options also must meet the criteria set forth in 21 CFR 312.305 (requirements for all expanded access uses).

**C. Expanded Access in CHC Context**

Some patients with CHC who have not responded to approved treatments and/or who are at substantial risk of

liver disease progression may benefit from access to new therapeutic options before approval through the Expanded Access Rule. On the other hand, receiving preapproval treatment access via a treatment protocol may have potential risks such as adverse reactions or the development of drug or drug-class resistance.

Historically, early access programs with antiretrovirals for the treatment of HIV allowed many people to gain access to life-saving drugs. For some individuals, however, early access to a drug resulted in what amounted to sequential monotherapy and the emergence of multidrug resistance. Similar to HIV treatment concerns, drug resistance and drug-class resistance are concerns for DAAs to treat CHC. Because treatment of CHC requires multiple agents to achieve acceptable SVR rates and to reduce the emergence of drug resistance to single agents or drug classes, treatment INDs that include two or more investigational agents or that allow for co-enrollment in several treatment IND programs are options to consider, particularly for previous null responders or for patients who cannot take interferon-based regimens. However, the use of multiple agents in the context of a treatment IND adds to the complexity of the implementation and design of treatment IND protocols. In light of the foregoing, FDA is soliciting advice from the public on how treatment access protocols for hepatitis C DAAs may best be designed.

**II. Scope of the Public Hearing**

FDA is interested in obtaining public comment on the following issues related to expanded access of DAAs for the treatment of CHC:

1. What types of patients with CHC are most appropriate for participation in DAA expanded access for CHC with regard to disease stage, previous treatment, and other disease characteristics?
2. Under what circumstances and in which populations would early access to a single DAA be appropriate?
3. Under what circumstances and in which populations would early access to multiple DAAs be appropriate?
4. How can pharmaceutical companies, government, academia, and community physicians and activists collaborate to provide for the treatment use of multiple new agents with the goal of maximizing response and reducing the emergence of drug or multidrug resistance?
5. What potential adverse reactions should be contemplated in formulating DAA treatment IND use protocols?

6. How can pharmaceutical companies, government, academia, and community physicians and activists collaborate to provide for the treatment use of multiple new agents with the goal of maximizing response and reducing adverse reactions?

7. In the course of developing DAAs for marketing, what types of studies should be conducted to best address unmet medical needs for patients with CHC including those with the greatest risk of progression of liver disease and/or the lowest predicted virologic response rates? Examples of studies that help to support clinical protocols or treatment use protocols in populations of unmet medical need may include renal and hepatic impairment studies and drug-drug interaction studies with antiretrovirals.

### III. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you wish to make an oral presentation during the hearing, you must register by submitting a written or electronic request by close of business on April 8, 2010, to Susie Dill (see **FOR FURTHER INFORMATION CONTACT**). You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, e-mail address, and type of organization you represent (e.g., industry, consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to Susie Dill (see **FOR FURTHER INFORMATION CONTACT**). We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). We will mail, e-mail, or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

If you need special accommodations due to a disability, please contact Susie Dill (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

### IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (21 CFR 15.30(e)). Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C), (21 CFR 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI of this document for more details). To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

### V. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments for consideration. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by the topic to which they refer. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript also will be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: March 2, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-5055 Filed 3-9-10; 8:45 am]

**BILLING CODE 4160-01-S**

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

#### Privacy Act of 1974; Retirement of Department of Homeland Security Federal Emergency Management Agency System of Records

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice of retirement of a Privacy Act system of records notice.

**SUMMARY:** In accordance with the Privacy Act of 1974 the Department of Homeland Security is giving notice that it proposes to retire Department of Homeland Security Federal Emergency Management Agency U.S. Fire Administration—001 9/11 Heroes Stamp Act of 2001 System of Records, July 26, 2005.

**DATES:** *Effective Date:* April 9, 2010.

**FOR FURTHER INFORMATION CONTACT:** For general questions please contact: Delia Davis (202-646-3808), Privacy Officer, Federal Emergency Management Agency, Department of Homeland Security, Washington, DC 20472. For privacy issues please contact: Mary Ellen Callahan (703-235-0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

**SUPPLEMENTARY INFORMATION:** Pursuant to the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) Federal Emergency Management Agency (FEMA) U.S. Fire Administration (USFA) is giving notice that it proposes to retire DHS/FEMA/USFA—001 9/11 Heroes Stamp Act of 2001 System of Records (70 FR 43218, July 26, 2005).