

treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. Subsequent to this approval, the USPTO received patent term restoration applications for OLYSIO (U.S. Patent Nos. 7,671,032 and 8,349,869) from Medivir AB and Janssen R&D Ireland, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OLYSIO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OLYSIO is 2,006 days. Of this time, 1,766 days occurred during the testing phase of the regulatory review period, while 240 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 28, 2008. FDA has verified the Medivir AB and Janssen R&D Ireland claim that May 28, 2008, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 28, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for OLYSIO (NDA 205123) was initially submitted on March 28, 2013.

3. *The date the application was approved:* November 22, 2013. FDA has verified the applicant's claim that NDA 205123 was approved on November 22, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension and amendments, the applicants seek 801 or 280 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination

(see DATES). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Science Advisory Board to the National Center for Toxicological Research; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research (NCTR) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Advisory Board to the National Center for Toxicological Research for an additional 2 years beyond the charter expiration date. The new charter will be in effect until June 2, 2018.

DATES: Authority for the Science Advisory Board to the National Center for Toxicological Research will expire on June 2, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna L. Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, donna.mendrick@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Science Advisory Board to the National Center for Toxicological Research advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility. The Board advises the Director, NCTR, in establishing, implementing, and evaluation the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of toxicological research. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ToxicologicalResearch/ucm148166.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-12657 Filed 5-27-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Facilitating Antibacterial Drug Development for Patients With Unmet Need and Developing Antibacterial Drugs That Target a Single Species Media; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding antibacterial drug development for patients with unmet need and developing antibacterial drugs that target a single species. FDA is interested in discussing the scientific challenges pertaining to such development programs, including enrollment challenges, clinical trial designs, and trial population. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. government Agencies, public health organizations, academic experts, and industry on various aspects of drug development for new antibacterial drugs for patients with unmet need and new antibacterial drugs that target a single species. The input from this public workshop will also help in developing topics for future discussion.

DATES: The public workshop will be held on July 18, 2016, from 8:30 a.m. to 5 p.m. and July 19, 2016, from 8:30 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221 Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding antibacterial drug development for patients with unmet need and developing antibacterial drugs that target a single species. Discussions will focus on potential development pathways, aspects of clinical trials including patient population, trial designs, and endpoints, and the role of clinical trial networks in antibacterial drug development.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to unmetneed2016@fda.hhs.gov. Persons without access to the Internet can call 301-796-1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Agenda: The workshop draft Agenda will be made available at: <http://www.fda.gov/Drugs/NewsEvents/ucm497650.htm> at least 2 days prior to the meeting. The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be available on the Internet at: <http://www.fda.gov/Drugs/NewsEvents/ucm497650.htm> approximately 45 days after the workshop.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on August 10, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, Patricio.Garcia@fda.hhs.gov, 301-796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* On August 10, 2016, the committee will discuss, make recommendations, and