of the brain. We require characteristic findings on microscopic examination of the cerebral spinal fluid or of the biopsied brain tissue to establish the diagnosis.

c. *Primary effusion lymphoma* (PEL, 114.11C) is also known as body cavity lymphoma. We require characteristic findings on microscopic examination of the effusion fluid or of the biopsied tissue from the affected internal organ to establish the diagnosis.

d. *Progressive multifocal leukoencephalopathy* (PML, 114.11D) is a progressive neurological degenerative syndrome caused by the JC virus in immunosuppressed children. Clinical findings of PML include clumsiness, progressive weakness, and visual and speech changes. Personality and cognitive changes may also occur. We require appropriate clinical findings, characteristic white matter lesions on MRI, and a positive PCR test for the JC virus in the cerebral spinal fluid to establish the diagnosis. We also accept a positive brain biopsy for JC virus to establish the diagnosis.

e. *Pulmonary Kaposi sarcoma* (Kaposi sarcoma in the lung, 114.11E) is the most serious form of Kaposi sarcoma (KS). Other internal KS tumors (for example, the gastrointestinal tract) have a more variable prognosis. We require characteristic findings on microscopic examination of the induced sputum or bronchoalveolar lavage washings, or of the biopsied transbronchial tissue, to establish the diagnosis.

4. *CD4 measurement (114.11F).* To evaluate your HIV infection under 114.11F, we require one measurement of your absolute CD4 count (also known as CD4 count or CD4+ T-helper lymphocyte count), for children from age 5 to attainment of age 18, or your CD4 percentage, for children from birth to attainment of age 5. This measurement (absolute CD4 count or CD4 percentage) must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one CD4 measurement within this period, we will use your lowest absolute CD4 count or CD4 percentage.

5. *Growth failure due to HIV immune suppression.* We evaluate linear growth failure under a growth impairment listing in 100.00. If your growth failure does not meet or medically equal the criteria of a listing in 100.00, we will consider whether your HIV infection meets or medically equals the criteria of a listing in another body system. For example, if your HIV infection has resulted in weight loss or a combination of weight loss and linear growth failure, we will evaluate your impairment under a digestive system listing in 105.00.

6. *Complications of HIV infection requiring hospitalization (114.11G).*

a. Complications of HIV infection may include infections (common or opportunistic), cancers, and other conditions. Examples of complications that may result in hospitalization include: Depression; diarrhea; immune reconstitution inflammatory syndrome; malnutrition; and *Pneumocystis* pneumonia and other severe infections.

b. Under 114.11G, we require three hospitalizations within a 12-month period resulting from a complication(s) of HIV infection. The hospitalizations may be for the same complication or different complications of HIV infection. All three hospitalizations must occur within the period we are considering in connection with your application or continuing disability review.

7. *Neurological manifestations specific to children (114.11H).* The methods of identifying and evaluating neurological manifestations may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In an older child, impaired brain growth may be documented by brain atrophy on a CT scan or MRI. Neurological manifestations in infants and young children may present in the loss of acquired developmental milestones (developmental regression) or, in school-age children and adolescents, the loss of acquired intellectual abilities. A child may demonstrate loss of intellectual abilities by a decrease in IQ scores, by forgetting information previously learned, by inability to learn new information, or by a sudden onset of a new learning disability. When infants and young children present with serious developmental delays (without regression), we evaluate the child's impairment(s) under 111.00.

* * * * *

114.11 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 114.00F1 and one of the following:

A. Multicentric Castleman disease (see 114.00F3a). OR

B. Primary central nervous system lymphoma (see 114.00F3b). OR

C. Primary effusion lymphoma (see 114.00F3c). OR

D. Progressive multifocal leukoencephalopathy (see 114.00F3d). OR

E. Pulmonary Kaposi sarcoma (see 114.00F3e). OR

F. Absolute CD4 count or CD4 percentage (see 114.00F4):

1. For children from birth to attainment of age 5, CD4 percentage of less than 15 percent; or

2. For children age 5 to attainment of age 18, absolute CD4 count of 50 cells/mm^3 or less. OR

G. Complications(s) of HIV infection requiring at least three hospitalizations within a 12-month period and at least 30 days apart (see 114.00F6). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. OR

H. A neurological manifestation of HIV infection (for example, HIV encephalopathy or peripheral neuropathy) (see 114.00F7) resulting in one of the following:

1. Loss of previously acquired developmental milestones or intellectual ability (including the sudden onset of a new learning disability), documented on two examinations at least 60 days apart; or

2. Progressive motor dysfunction affecting gait and station or fine and gross motor skills, documented on two examinations at least 60 days apart; or

3. Microcephaly with head circumference that is less than the third percentile for age, documented on two examinations at least 60 days apart; or

4. Brain atrophy, documented by appropriate medically acceptable imaging.

[FR Doc. 2014–04124 Filed 2–25–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2013–N–0402]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2015 Regulatory Science Plan.

DATES: The public hearing will be held on May 16, 2014, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

ADDRESSES: The public hearing will be held at the FDA 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 hearing 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: Thushi Amini, Center for Drug Evaluation and Research, Food and

Drug Administration, 7520 Standish Pl., MPN–1, Rm. 1444, Rockville, MD 20855, 240–276–8810, email: *Thushi.Amini@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., MPN–1, Rm. 1449, Rockville, MD 20855, 240–276–8619, email: *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Webcast (see *Streaming Webcast of the Public Hearing*)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to *GDUFARegulatoryScience@fda.hhs.gov* by April 25, 2014. The email should contain complete contact information for each attendee (i.e., name, title, affiliation, address, email address, and telephone number). Those without email access can register by contacting Thushi Amini by April 25, 2014 (see *Contact Person*).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section IV). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to *GDUFARegulatoryScience@fda.hhs.gov* on or before May 9, 2014. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and other background materials will be made available 5 days before the hearing at *http://www.fda.gov/Drugs/NewsEvents/ucm344710.htm.*

If you need special accommodations because of a disability, please contact Thushi Amini (see *Contact Person*) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to *https://collaboration.fda.gov/regscipart15/.*

Comments: Regardless of attendance at the public hearing, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), 5600 Fishers Lane, Rm. 1061, Rockville, MD 20857. The deadline for submitting comments to the docket is June 13, 2014. It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may also be viewed at the Division of Dockets Management (see *Comments*). A transcript will also 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 (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012–2017. The commitment letter can be found at *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.*

II. FY 2013 Regulatory Science Priorities

The FY 2013 regulatory science research priorities list was developed by FDA and industry and included in the GDUFA commitment letter. To implement the FY 2013 priorities list, the Office of Generic Drugs awarded $17 million in external contracts and grants to initiate new research studies during FY 2013. Four million dollars were allocated to support internal research related to generic drugs. This includes rapid response capabilities through equipment for FDA labs and support for laboratory research fellows at FDA, as well as research fellows to work on data analysis and coordination of internal activities with external grants and contracts.

III. FY 2014 Regulatory Science Priorities

On June 21, 2013, the Office of Generic Drugs held a public hearing to gain input in developing the FY 2014 regulatory science priorities list. This list was prepared based on internal Center for Drug Evaluation and Research discussions, comments received from this public hearing, and comments submitted to the public docket.

The FY 2014 Regulatory Science Priorities are as follows:

1. Postmarket evaluation of generic drugs,
2. Equivalence of complex products,
3. Equivalence of locally acting products,
4. Therapeutic equivalence evaluation and standards, and
5. Computational and analytical tools.

For more information on these topic areas, please visit *http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm.*

IV. Purpose and Scope of the May 16, 2014, Public Hearing

The purpose of the May 2014 public hearing is to obtain input from industry and other interested stakeholders on the identification of regulatory science priorities for FY 2015. To help fulfill FDA's mission, FDA is particularly interested in receiving input on the following topics:

1. Current regulatory science challenges that limit the availability of generic drugs,
2. Regulatory science approaches to improve the preapproval evaluation of therapeutic equivalence of generic drugs,
3. Postapproval regulatory science approaches to ensure the therapeutic equivalence of approved generic drugs,
4. Prioritization of FY 2015 regulatory science research topics for generic drugs based on public health impact, and
5. The need for additional or revised draft guidance to clarify FDA's scientific recommendations related to generic drug development.

FDA will consider all comments made at this hearing or received through the docket (see *Comments*) as it develops its FY 2015 GDUFA Regulatory Science Plan. Additional information concerning GDUFA, including the text

of the law and the commitment letter can be found on the FDA Web site at *http://www.fda.gov/gdufa*.

V. 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 pose questions; they may question any person during or at the conclusion of each presentation. 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, subpart C) (21 CFR Part 10, subpart C)). Under § 10.205, representatives of the 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 *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

Dated: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03986 Filed 2–25–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2014–0003; Notice No. 142]

RIN 1513–AC05

Proposed Establishment of The Rocks District of Milton–Freewater Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to establish the approximately 3,770-acre ''The Rocks District of Milton–Freewater'' viticultural area in Umatilla County, Oregon. The proposed viticultural area lies entirely within the Walla Walla Valley viticultural area which, in turn, lies within the Columbia Valley viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. TTB invites comments on this proposed addition to its regulations.

DATES: Comments must be received by April 28, 2014.

ADDRESSES: Please send your comments on this notice to one of the following addresses:

- *Internet: http://www.regulations.gov* (via the online comment form for this notice as posted within Docket No. TTB–2014–0003 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or
- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, selected supporting materials, and any comments that TTB receives about this proposal at *http://www.regulations.gov* within Docket No. TTB–2014–0003. A link to that docket is posted on the TTB Web site at *http://www.ttb.gov/wine/wine-rulemaking.shtml* under Notice No. 142. You also may view copies of this notice, all related petitions, maps, or other supporting materials, and any comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. Please call 202–453–2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR Part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR Part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and a name and a delineated boundary as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs.