TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	H. Software/Informatics	
13–82	Application of risk management for IT networks incorporating medical—Application guidance—Part 2–6: Guidance for responsibility agreements.	AAMI/ISO TIR 80001–2–6:2014.
13–83	Principles for medical device security—Risk management	AAMI TIR 57:2016.
13–84	Health informatics—Point-of-care medical device communication—Part 10103: Nomenclature—Implantable device, cardiac.	ISO/IEEE 11073–10103 First edition 2014–03–01.
	I. Tissue Engineering	
15–45	Medical devices utilizing animal tissues and their derivatives—Part 1: Application of risk management.	ISO 22442–1 Second edition 2015–11–1.
15–46	Medical devices utilizing animal tissues and their derivatives—Part 2: Controls on sourcing, collection and handling.	ISO 22442–2 Second edition 2015–11–1.
15–47	Medical devices utilizing animal tissues and their derivatives—Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents.	ISO 22442–3 First edition 2007–12–15.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *standards@cdrh.fda.gov.* To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 043'' will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15100 Filed 6–24–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1170]

Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Draft Guidance for Industry; Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of availability, published in the **Federal Register** of May 4, 2016 (81 FR 26805), announcing the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' We are taking this action due to maintenance on the Federal eRulemaking portal from July 1 through July 5, 2016.

DATES: Submit either electronic or written comments by July 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are

solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1170 for ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 4, 2016 (81 FR 26805), FDA published a notice of availability.

Interested persons were originally given until July 5, 2016, to comment on the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.''

From July 1 through July 5, 2016, the Federal eRulemaking Portal, *http://www.regulations.gov*, is undergoing maintenance. We are, therefore, extending the comment period for the draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The extended comment period will close on July 19, 2016.

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–15098 Filed 6–24–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 27, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Black Lung Clinics Program Performance Measures OMB No. 0915–0292–Extension

Abstract: HRSA's Federal Office of Rural Health Policy (FORHP), conducts an annual data collection of information for the Black Lung Clinics Program, which has been ongoing with OMB approval since 2004. The Black Lung Clinics Program seeks to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease. Collecting this data provides HRSA with information on the extent to which each grantee is meeting the needs of these miners in their communities.

Need and Proposed Use of the Information: Data from the annual report provides quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits