INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *Stephen.Ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' The draft guidance discusses the following major topics: (1) Applicability of part 312 (21 CFR part 312) to studies using RWD and (2) regulatory considerations for non-interventional (observational) studies using RWD. Topics covered under regulatory considerations include the following: (1) Transparency for data collection and analysis, (2) data access, (3) study monitoring, (4) safety reporting, and (5) sponsor responsibilities.

Section 3022 of the 21st Century Cures Act (Cures Act) amended the FD&C Act to add section 505F, Utilizing Real World Evidence (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help support or satisfy postapproval study requirements. This section also requires that FDA utilize the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA is committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. FDA is issuing the draft guidance entitled ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products'' as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI commitment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 54 have been approved under OMB control number 0910–0396. The collections of information in 21 CFR part 310 have been approved under OMB control number 0910–0230. The collections of information in 21 CFR parts 310, 314, and 600 have been approved under OMB control number 0910–0645. The collections of information in 21 CFR parts 310, 314, and 600 have been approved under OMB control number 0910–0291. The collections of information in part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 600 have been approved under OMB control number 0910–0458. The collections of information in FDA's guidance for industry entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733. The collections of information in FDA's guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products'' have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 2, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26640 Filed 12–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 056

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 056'' (Recognition List Number: 056), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable December 9, 2021.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 056.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 056.

• 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

An electronic copy of Recognition List Number: 056 is available on the internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 056 modifications and other standards-related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 056'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301–796–6287, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In the **Federal Register** of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.'' The guidance describes how FDA has implemented its standards recognition program and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.* Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains on its website hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards, available at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.* Additional information on the Agency's Standards and Conformity Assessment Program is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 056

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term ''Recognition List

Number: 056'' to identify the current modifications.

In table 1, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 056.

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. Anesthesiology			
1–115	1–151	ISO 80601–2–70 Second edition 2020–11 Medical electrical equipment—Part 2–70: Particular requirements for the basic safety and essential performance of sleep apnea breathing therapy equipment.	Withdrawn and replaced with newer version.
B. Biocompatibility			
2–191	2–289	ISO 10993–12 Fifth edition 2021–01 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials.	Withdrawn and replaced with newer version.
2–241		ISO/TR 37137 First edition 2014–05–15 Cardiovascular biological evaluation of medical devices—Guidance for absorbable implants.	Withdrawn. See 2–290.
C. Cardiovascular			
3–92	3–170	ISO 14708–5 Second edition 2020–05 Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices.	Withdrawn and replaced with newer version.
3–129		ANSI/AAMI EC53:2013/(R)2020 ECG trunk cables and patient leadwires.	Extent of recognition.
3–166		ISO 81060–2 Third edition 2018–11 Noninvasive sphygmomanometers—Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)].	Extent of recognition.
3–168		IEEE Std 1708–2014 Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including: Amendment 1 (2019)].	Extent of recognition.
D. Dental/Ear, Nose, and Throat (ENT)			
4–105		ANSI/ADA Standard No. 75—1997 (R2014) Resilient Lining Materials for Removable Dentures, Part 1: Short-Term Materials.	Withdrawn.
4–164	4–273	ANSI/ASA S3.7–2016 (Reaffirmed 2020) American National Standard Method for Measurement and Calibration of Earphones.	Withdrawn and replaced with newer version.
4–183	4–274	ANSI/ASA S3.2–2020 American National Standard Method for Measuring the Intelligibility of Speech over Communication Systems.	Withdrawn and replaced with newer version.
4–194		ANSI/ADA Standard No. 78—2006 Dental obturating cones (Modified adoption of ISO 6877–1:1995, Dental obturating points).	Withdrawn.
4–195		ISO 14801 Second edition 2007–11–15 Dentistry—Implants—Dynamic fatigue test for endosseous dental implants.	Withdrawn.
4–203	4–275	ANSI/ASA S3.6–2018 American National Standard Specification for Audiometers.	Withdrawn and replaced with newer version.
4–206	4–276	ISO 14457 Second edition 2017–10 Dentistry—Handpieces and motors.	Withdrawn and replaced with newer version.
4–216	4–277	ANSI/IEEE C63.19–2019 American National Standard Methods of Measurement of Compatibility between Wireless Communication Devices and Hearing Aids.	Withdrawn and replaced with newer version.
4–225	4–278	ISO 4823 Fifth edition 2021–02 Dentistry—Elastomeric impression and bite registration materials.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
No new entries at this time.			
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–23	19–40	IEC 60086–4 Edition 5.0 2019–04 Primary batteries—Part 4: Safety of lithium batteries [Including: Corrigendum 1 (2019) and Corrigendum 2 (2020)].	Withdrawn and replaced with newer version.

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–385	6–461	IEC 60601–2–19 Edition 3.0 2020–09 Medical electrical equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators.	Withdrawn and replaced with newer version.
6–386	6–462	IEC 60601–2–20 Edition 3.0 2020–09 Medical electrical equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators.	Withdrawn and replaced with newer version.
6–388	6–463	IEC 60601–2–21 Edition 3.0 2020–09 Medical electrical equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers.	Withdrawn and replaced with newer version.
6–389		IEC 60601–2–2 Edition 6.0 2017–03 Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.	Extent of recognition.
H. In Vitro Diagnostics (IVD)			
7–193	7–306	CLSI EP06 2nd Edition Evaluation of the Linearity of Quantitative Measurement Procedures.	Withdrawn and replaced with newer version.
7–209	7–307	CLSI POCT05 2nd Edition Performance Metrics for Continuous Interstitial Glucose Monitoring.	Withdrawn and replaced with newer version.
7–236		CLSI M43–A October 2011 Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline.	Extent of recognition.
7–262		CLSI M45 3rd Edition Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria.	Extent of recognition.
7–292		CLSI M62 1st Edition Performance Standards for Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes.	Extent of recognition.
7–294	7–308	CLSI M100 31st Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
I. Materials			
8–394	8–555	ASTM F1472–20a Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Withdrawn and replaced with newer version.
8–418	8–556	ASTM F640–20 Standard Test Methods for Determining Radiopacity for Medical Use.	Withdrawn and replaced with newer version.
8–445		ISO 17296–4 First edition 2014–09–01 Additive manufacturing—General principles—Part 4: Overview of data processing.	Withdrawn. See 8–561.
8–486	8–557	ASTM F3268—18a Standard Guide for in vitro Degradation Testing of Absorbable Metals.	Withdrawn and replaced with newer version.
8–490		ASTM F3303–18 Standard for additive manufacturing—Process characteristics and performance—Practice for metal powder bed fusion process to meet critical applications.	Withdrawn. See 8–562.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9–39	9–131	ISO 8600–5 Second Edition 2020–10 Optics and photonics—Medical endoscopes and endotherapy devices—Part 5: Determination of optical resolution of rigid endoscopes with optics.	Withdrawn and replaced with newer version.
9–44	9–132	ASTM F623–19 Standard Performance Specification for Foley Catheter.	Withdrawn and replaced with newer version.
9–53		ASTM F1992–99 (Reapproved 2007) Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes.	Withdrawn.
9–95		CENEN 1615:2000 Enteral Feeding Catheters and Enteral Giving Sets for Single Use and their Connectors-Design and Testing.	Withdrawn. See 9–138.
9–97		ISO 13958 Third edition 2014–04–01 Concentrates for haemodialysis and related therapies.	Withdrawn. See 9–136.

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
9–98		ISO 13959 Third edition 2014–04–01 Water for haemodialysis and related therapies.	Withdrawn. See 9–135.
9–99		ISO 23500 Second edition 2014–04–01 Guidance for the preparation and quality management of fluids for haemodialysis and related therapies.	Withdrawn. See 9–133.
9–100		ISO 11663 Second edition 2014–04–01 Quality of dialysis fluid for haemodialysis and related therapies.	Withdrawn. See 9–137.
9–101		ISO 26722 Second edition 2014–04–01 Water treatment equipment for haemodialysis applications and related therapies.	Withdrawn. See 9–134.
9–113		CENEN 1618:1997 Catheters other than intravascular catheters—Test methods for common properties.	Withdrawn. See 9–138.
		M. Ophthalmic	
10–35	10–122	ISO 10939 Third edition 2017–05 Ophthalmic instruments—Slit-lamp microscopes.	Withdrawn and replaced with newer version.
10–72	10–123	ISO 15004–1 Second edition 2020–5 Ophthalmic instruments—Fundamental requirements and test methods—Part 1: General requirements applicable to all ophthalmic instruments.	Withdrawn and replaced with newer version.
10–79	10–124	ISO 11979–1 Fourth edition 2018–11 Ophthalmic implants—Intraocular lenses—Part 1: Vocabulary.	Withdrawn and replaced with newer version.
10–81	10–125	ISO 11979–7 Fourth edition 2018–03 Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations of intraocular lenses for the correction of aphakia.	Withdrawn and replaced with newer version.
10–90		ISO 11979–9 First edition 2006–09–01 Ophthalmic implants—Intraocular lenses—Part 9: Multifocal intraocular lenses [Including: Amendment 1 (2014)].	Withdrawn.
		N. Orthopedic	
11–238	11–376	ASTM F2033–20 Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials.	Withdrawn and replaced with newer version.
11–258	11–377	ASTM F2083–21 Standard Specification for Knee Replacement Prosthesis.	Withdrawn and replaced with newer version.
11–270	11–378	ASTM F2502–17 Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants.	Withdrawn and replaced with newer version.
11–285	11–379	ASTM F2978–20 Standards Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
11–286	11–380	ASTM F2979–20 Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses.	Withdrawn and replaced with newer version.
11–293	11–381	ASTM F2582–20 Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components.	Withdrawn and replaced with newer version.
		O. Physical Medicine	
		No new entries at this time.	
		P. Radiology	
12–260	12–335	IEC 60336 Edition 5.0 2020–12 Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Focal spot dimensions and related characteristics.	Withdrawn and replaced with newer version.
12–269	12–336	IEC 60601–1–3 Edition 2.2 2021–01 CONSOLIDATED VERSION Medical electrical equipment—Part 1–3: General requirements for basic safety and essential performance—Collateral Standard: Radiation protection in diagnostic X-ray equipment.	Withdrawn and replaced with newer version.
12–284	12–337	NEMA NU 1–2018 Performance Measurements of Gamma Cameras.	Withdrawn and replaced with newer version.
12–285	12–338	IEC 60601–2–1 Edition 4.0 2020–10 Medical electrical equipment—Part 2–1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV.	Withdrawn and replaced with newer version.
12–310	12–339	IEC 60601–2–63 Edition 1.2 2021–05 CONSOLIDATED VERSION Medical electrical equipment—Part 2–63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.	Withdrawn and replaced with newer version.

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
12–311	12–340	IEC 60601–2–65 Edition 1.2 2021–05 CONSOLIDATED VERSION Medical electrical equipment—Part 2–65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14–511	14–562	ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities.	Withdrawn and replaced with newer version.
S. Tissue Engineering			
15–10		ASTM F2451–05 (Reapproved 2010) Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage.	Withdrawn.
15–32	15–66	ASTM F2260–18 Standard Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (1HNMR) Spectroscopy.	Withdrawn and replaced with newer version.
15–60	15–67	ASTM F2212–20 Standard Guide for Characterization of Type I Collagen as Starting Materials for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs).	Withdrawn and replaced with newer version.

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

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 056. These entries are of standards not previously recognized by FDA.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
No new entries at this time.		
B. Biocompatibility		
2–290	Biological evaluation of absorbable medical devices—Part 1: General requirements.	ISO/TS 37137–1 First edition 2021–03.
2–291	Biological evaluation of medical devices—Part 23: Tests for irritation	ISO 10993–23 First edition 2021–01.
C. Cardiovascular		
No new entries at this time		
D. Dental/Ear, Nose, and Throat (ENT)		
4–279	Part 1: Disposable Prophy Angles	ANSI/ADA Standard No. 85–2004 (R2009).
4–280	Fluoride Varnishes	ANSI/ADA Standard No. 117–2018.
4–281.	Dentistry—Shanks for rotary and oscillating instruments	ISO 1797 Third edition 2017–05.
4–282	Dentistry—Denture adhesives	ISO 10873 First edition 2010–09.
4–283	Dentistry—Oral care products—Manual interdental brushes	ISO 16409 Second edition 2016–10.
E. General I (Quality Systems/Risk Management) (QS/RM)		
No new entries at this time.		
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
No new entries at this time.		
G. General Hospital/General Plastic Surgery (GH/GPS)		
6–460	Standard Specification for Barrier Face Coverings	ASTM F3502–21.

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

Recognition No.	Title of standard [1]	Reference No. and date
	H. In Vitro Diagnostics (IVD)	
	No new entries at this time.	
	I. Materials	
8–558	Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	ASTM F3333–20.
8–559	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension.	ASTM D412–16e1.
8–560	Standard Test Method for Rubber Property—International Hardness	ASTM D1415–18.
8–561	Additive manufacturing—General principles—Overview of data processing	ISO/ASTM 52950 First edition 2021–01.
8–562	Additive manufacturing—Process characteristics and performance—Practice for metal powder bed fusion process to meet critical applications.	ISO/ASTM 52904 First edition 2019–08.
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
9–133	Preparation and quality management of fluids for haemodialysis and related therapies—Part 1: General requirements.	ISO 23500–1 First edition 2019–02.
9–134	Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies.	ISO 23500–2 First edition 2019–02.
9–135	Preparation and quality management of fluids for haemodialysis and related therapies—Part 3: Water for haemodialysis and related therapies.	ISO 23500–3 First edition 2019–02.
9–136	Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies.	ISO 23500–4 First edition 2019–02.
9–137	Preparation and quality management of fluids for haemodialysis and related therapies—Part 5: Quality of dialysis fluid for haemodialysis and related therapies.	ISO 23500–5 First edition 2019–02.
9–138	Enteral feeding systems—Design and testing	ISO 20695 First edition 2020–03.
	M. Ophthalmic	
10–126	Medical electrical equipment—Part 2–58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery [Including AMENDMENT 1 (2016)].	IEC 80601–2–58 Edition 2.0 2014–09.
	N. Orthopedic	
11–382	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement.	ASTM F3090–20.
11–383	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings under Standard Conditions Using a Reciprocal Friction Simulator.	ASTM F3143–20.
11–384	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator.	ASTM F3446–20.
	O. Physical Medicine	
16–231	Prosthetics—Structural testing of lower-limb prostheses—Requirements and test methods.	ISO 10328 Second edition 2016–06–01.
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
13–117	Health informatics—Device interoperability Part 40101: Foundational—Cybersecurity—Processes for vulnerability assessment.	IEEE Std 11073–40101–2020.
13–118	Health informatics—Device interoperability Part 40102: Foundational—Cybersecurity—Capabilities for mitigation.	IEEE Std 11073–40102–2020.
13–119	Security for industrial automation and control systems Part 4–1: Product security development life-cycle requirements..	ANSI/ISA–62443–4–1–2018.

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

Recognition No.	Title of standard [1]	Reference No. and date
	R. Sterility	
	No new entries at this time.	
	S. Tissue Engineering	
	No new entries at this time.	

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

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). 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.

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 *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26635 Filed 12–8–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection aspects of the Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.

DATES: Submit either electronic or written comments on the collection of information by February 7, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 7, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 7, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2011–D–0125 for ''Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential