NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: February 25, 2021.

Patrizia Cavazzoni,

Acting Director, Center for Drug Evaluation and Research.

[FR Doc. 2021–04344 Filed 3–2–21; 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: 054

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: 054'' (Recognition List Number: 054), 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 March 3, 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: http://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: 054.'' 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: 054.

- 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: 054 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: 054 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: 054'' 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: 054

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: 054'' 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: 054.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–98	1–146	ISO 80601–2–12 Second edition 2020–02 Medical electrical equipment—Part 2–12: Particular requirements for basic safety and essential performance of critical care ventilators.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–168	2–273	ISO 10993–9 Third edition 2019–11 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	Withdrawn and replaced with newer version. Extent of recognition.
2–197	2–274	ASTM F749—20 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit.	Withdrawn and replaced with newer version.
2–238		ANSI/AAMI BE83:2006/(R)2011 Biological evaluation of medical devices—Part 18: Chemical characterization of materials.	Withdrawn.
		C. Cardiovascular	
3–55	3–164	ASTM F1830—19 Standard Practice for Collection and Preparation of Blood for Dynamic In Vitro Evaluation of Blood Pumps.	Withdrawn and replaced with newer version.
3–56	3–165	ASTM 1841—19 Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps.	Withdrawn and replaced with newer version.
3–127	3–155	ANSI/AAMI/IEC 60601–2–47:2012/(R)2016 Medical electrical equipment—Part 2–47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.	Transferred.
3–142	8–525	ISO/TS 17137 Second edition 2019–09 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants.	Withdrawn and replaced with newer version. Transferred.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
3–152	3–123	IEC 80601–2–30: Edition 2.0 2018–03 Medical electrical equipment Part 2–30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers.	Withdrawn and replaced with newer version.
3–160	3–166	ISO 81060–2 Third edition 2018–11 Non-invasive sphygmomanometers—Part 2: Clinical investigation of intermittent automated measurement type [Including AMENDMENT1 (2020)].	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4–201	4–263	ISO 9693 Third edition 2019–10 Dentistry—Compatibility testing for metal-ceramic and ceramic-ceramic systems.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–110	5–126	ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	Withdrawn and replaced with newer version.
5–111	5–127	ISTA 3B 2017 Packaged-Products for Less-Than-Truckload (LTL) Shipment.	Withdrawn and replaced with newer version.
5–112	5–128	ISTA 3E 2017 Similar Packaged-Products in Unitized Loads of Truckload Shipment.	Withdrawn and replaced with newer version.
5–114	5–129	IEC 62366–1 Edition 1.1 2020–06 CONSOLIDATED VERSION Medical devices—Part 1: Application of usability engineering to medical devices.	Withdrawn and replaced with newer version.
5–116	5–130	ISO 7010 Third edition 2019–07 Graphical symbols—Safety colours and safety signs—Registered safety signs.	Withdrawn and replaced with newer version.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
No new entries at this time.			
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–68	6–439	ISO 7886–2 Second edition 2020–04 Sterile hypodermic syringes for single use—Part 2: Syringes for use with power-driven syringe pumps.	Withdrawn and replaced with newer version.
6–145	6–440	ASTM D3578—19 Standard Specification for Rubber Examination Gloves.	Withdrawn and replaced with newer version.
6–148	6–441	ISO 7886–3 Second edition 2020–05 Sterile hypodermic syringes for single use—Part 3: Auto-disabled syringes for fixed-dose immunization.	Withdrawn and replaced with newer version.
6–165	6–442	ASTM D6977—19 Standard Specification for Polychloroprene Examination Gloves for Medical Application.	Withdrawn and replaced with newer version.
6–168	6–443	ASTM D3577—19 Standard Specification for Rubber Surgical Gloves.	Withdrawn and replaced with newer version.
6–176	6–444	ASTM D7103—19 Standard Guide for Assessment of Medical Gloves.	Withdrawn and replaced with newer version.
6–178	.....	ASTM D6124—06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.	Extent of recognition.
6–183	6–445	ASTM D5250—19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.	Withdrawn and replaced with newer version.
6–244	6–446	ASTM D6319—19 Standard Specification for Nitrile Examination Gloves for Medical Application.	Withdrawn and replaced with newer version.
6–318	6–447	ISO 8536–4 Sixth edition 2019–09 Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
No new entries at this time.			
I. Materials			
8–227	8–526	ASTM F2182—19ε2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
8–343	8–527	ASTM F899—20 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with newer version.
8–349	8–528	ASTM F2503—20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–374	8–529	ASTM F2633—19 Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants.	Withdrawn and replaced with newer version.
8–461	8–530	ASTM F3208—19 Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.	Withdrawn and replaced with newer version.
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)			
No new entries at this time.			
M. Ophthalmic			
No new entries at this time.			
N. Orthopedic			
11–215	11–363	ASTM F897—19 Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws.	Withdrawn and replaced with newer version.
11–222	11–364	ISO 14243–1 Second edition 2009–11–15 Implants for surgery—Wear of total knee-joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test [Including AMENDMENT1 (2020)].	Withdrawn and replaced with newer version.
11–253	11–365	ASTM F1800—19ε1 Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements.	Withdrawn and replaced with newer version.
11–275	11–366	ASTM F2381—19 Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy.	Withdrawn and replaced with newer version.
11–292	11–367	ISO 14243–3 Second edition 2014–11–01 Implants for surgery—Wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test [Including AMENDMENT 1 (2020)].	Withdrawn and replaced with newer version.
O. Physical Medicine			
16–170	.....	ANSI RESNA WC–1:2009 Section 3 American National Standard for Wheelchairs—Volume 1: Additional Requirements for Wheelchairs (including Scooters) Section 3: Determination of effectiveness of brakes.	Title change.
P. Radiology			
12–287	12–330	NEMA Standards Publication XR 28–2018 Supplemental Requirements for User Information and System Function Related to Dose in CT.	Withdrawn and replaced with newer version.
12–325	.....	NEMA Standards Publication XR 25–2019 Computed Tomography Dose Check.	Transition period extended.
Q. Software/Informatics			
13–80	13–113	IEEE Std 11073–20601–2019 Health informatics—Personal health device communication—Part 20601: Application profile—Optimized exchange protocol.	Withdrawn and replaced with newer version.
13–110	13–114	IEEE Std 11073–10101–2019 Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.	Withdrawn and replaced with newer version.
R. Sterility			
14–313	14–539	ASTM F2475—20 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–327	14–540	ISO 11737–2 Third edition 2019–12 Sterilization of health care products—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.	Withdrawn and replaced with newer version.
14–360	14–541	ANSI/AAMI ST72:2019 Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing.	Withdrawn and replaced with newer version.
14–408	2–275	ISO 10993–7 Second edition 2008–10–15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals [Including Corrigendum 1 (2009) and AMENDMENT 1 (2020)].	Withdrawn and replaced with newer version. Transferred.
14–436	14–542	ISO/ASTM 52628 Second edition 2020–04 Standard practice for dosimetry in radiation processing.	Withdrawn and replaced with newer version.
14–515		ISO 17664 Second edition 2017–10 Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices.	Extent of recognition.
14–528	14–543	ISO 11139 First edition 2018–08 Sterilization of health care products—Vocabulary of terms used in sterilization and related equipment and process standards.	New recognition number.
14–529	14–544	ISO 18472 Second edition 2018–08 Sterilization of health care products—Biological and chemical indicators—Test equipment.	New recognition number.
14–530	14–545	ISO/ASTM 51276 Fourth edition 2019–08 Practice for use of a polymethylmethacrylate dosimetry system.	New recognition number.
14–531	14–546	USP 42–NF37:2019 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	New recognition number.
14–532	14–547	USP 42–NF37:2019 <71> Sterility Tests	New recognition number.
14–533	14–548	USP 42–NF37:2019 <85> Bacterial Endotoxins Test	New recognition number.
S. Tissue Engineering			
15–19	15–59	ASTM F2450—18 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products.	Withdrawn and replaced with newer version.
15–30	15–60	ASTM F2212—19 Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs).	Withdrawn and replaced with newer version.
15–39	15–61	ASTM F2150 19 Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products.	Withdrawn and replaced with newer version.
15–41	15–62	ASTM F2602—18 Standard Test Method for Determining the Molar Mass of Chitosan and Chitosan Salts by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	Withdrawn and replaced with newer version.
15–50	15–63	ASTM F2739—19 Standard Guide for Quantifying Cell Viability and Related Attributes within Biomaterial Scaffolds.	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: 054. 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		
2–276	Biological evaluation of medical devices—Part 18: Chemical characterization of medical device materials within a risk management process.	ISO 10993–18 Second edition 2020–01.
C. Cardiovascular		
3–167	Non-invasive sphygmomanometers—Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers.	ISO/TS 81060–5 First edition 2020–02.

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

Recognition No.	Title of standard [1]	Reference No. and date
3–168	Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including Amendment 1 (2019)].	IEEE Std 1708–2014.
D. Dental/Ear, Nose, and Throat (ENT)		
No new entries at this time.		
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)		
No new entries at this time.		
H. In Vitro Diagnostics (IVD)		
7–296	Measurement Procedure Comparison and Bias Estimation Using Patient Samples.	CLSI EP09c 3rd Edition.
7–297	Medical laboratories—Practical guidance for the estimation of measurement uncertainty.	ISO/TS 20914 First edition 2019–07.
7–298	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.	CLSI EP35 1st Edition.
I. Materials		
8–531	Standard Guide for Methods of Extraction of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices.	ASTM F3321—19.
8–532	Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion.	ASTM F3335—20.
8–533	Additive Manufacturing—Feedstock materials—Methods to characterize metal powders.	ISO/ASTM 52907: First Edition 2019–11.
8–534	Additive Manufacturing—Design—Part 1: Laser-based powder bed fusion of metals.	ISO/ASTM 52911–1: First Edition 2019–07.
8–535	Additive Manufacturing—Design—Part 2: Laser-based powder bed fusion of polymers.	ISO/ASTM 52911–2: First Edition 2019–09.
8–536	Additive Manufacturing—Test Artifacts—Geometric capability assessment of additive manufacturing systems.	ISO/ASTM 52902: First Edition 2019–07.
J. Nanotechnology		
18–15	Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles..	ASTM E3025—16.
18–16	Nanotechnologies—Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation.	ISO/TS 21362 First edition 2018–06.
K. Neurology		
No new entries at this time.		
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)		
9–124	Colorimetry—Part 1: CIE standard colorimetric observers	ISO/CIE 11664–1 First edition 2019–06.
9–125	Colorimetry—Part 2: CIE standard illuminants	ISO 11664–2 CIE S 014–2/E First edition 2007–10–15 Corrected version 2008–11–01.
9–126	Colorimetry—Part 3: CIE tristimulus values	ISO/CIE 11664–3 First edition 2019–06.
9–127	Colorimetry—Part 4: CIE 1976 L*a*b* colour space	ISO/CIE 11664–4 First edition 2019–06.
9–128	Colorimetry—Part 6: CIEDE2000 colour-difference formula	ISO/CIE 11664–6 First edition 2014–02–01.
9–129	Multimedia systems and equipment—Colour measurement and management—Part 2–1: Colour management—Default RGB colour space—sRGB [Including Amendment 1 (2003) and Corrigendum 1 (2014)].	IEC 61966–2–1 First edition 1999–10.

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

Recognition No.	Title of standard [1]	Reference No. and date
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
11–368	Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components.	ASTM F3334—19.
11–369	Standard Practice for Inspection of Spinal Implants Undergoing Testing	ASTM F3292—19.
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
12–331	Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems.	NEMA Standards Publication MS 14–2019.
12–332	Magnetic resonance equipment for medical imaging—Part 1: Determination of essential image quality parameters.	IEC 62464–1 Edition 2.0 2018–12.
12–333	Guidance on error and warning messages for software used in radiotherapy	IEC TR 63183 Edition 1.0 2019–12.
12–334	Radiation therapy machine characterization	AAMI RT3:2020.
	Q. Software/Informatics	
13–115	Software and systems engineering—Software testing—Part 1: Concepts and definitions.	ISO/IEC/IEEE 29119–1 First edition 2013–09–01.
	R. Sterility	
14–549	Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound.	ASTM F3004—13ε1.
	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 listed on FDA's website, which is specifically available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–04376 Filed 3–2–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1638]

Lawrence B. Ryan: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Lawrence B. Ryan from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Ryan was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Ryan was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. As of October 18, 2020 (30 days after receipt of the notice), Mr. Ryan had not responded. Mr. Ryan's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable March 3, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers