for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Data from MA–PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

Sections 11001 through 11004 of the Inflation Reduction Act of 2022 establish a Medicare Drug Negotiation Program for high-expenditure drugs. Section 11102 of the Inflation Reduction Act of 2022 establishes a Part D inflation rebate by manufacturers of certain single source drugs and biologicals with prices increasing at a rate faster than the rate of inflation. CMS will use data reported under sections 1860D–15(c)(1)(C) and (d)(2), in part, to rank drugs by total expenditures under Part D in order to select drugs for negotiation and to identify units to calculate inflation rebates.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, and the PDPs, MA–PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development. *Form Number:* CMS–10174 (OMB control number: 0938–0982); *Frequency:* Monthly; *Affected Public:* Private sector and Federal Government; *Number of Respondents:* 856; *Total Annual Responses:* 1,499,064,780; *Total Annual Hours:* 62,918. (For policy questions regarding this collection contact Shelly Winston at 410–786–3694.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, title 42, part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities.

The information collected on IRs is used by Part- A Medicare Administrative Contractors (MAC) to verify the number of IRs FTE used in the calculation of Medicare payments for IME and GME. The IR data submitted by the hospitals to the MACs is uploaded into CMS' Intern and Resident Information System (IRIS) database to identify duplicate FTEs reported for any IR.

The MACs use the information collected on IRs to ensure that all program payments for IME and GME are accurate and are in accordance with Medicare regulations. The IR data submitted by the hospitals to the MACs are used to audit the Medicare cost reports filed by the hospitals. *Form Number:* CMS–R–64 (OMB control number: 0938–0456); *Frequency:* Monthly; *Affected Public:* Private sector and Federal Government; *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410–786–7550.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–04341 Filed 2–29–24; 8:45 am]

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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: 061

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: 061'' (Recognition List Number: 061), 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 1, 2024.

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: 061.'' 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: 061.

• 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: 061 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: 061 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: 061'' to Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–2503. 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: Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–2503, *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 of the FD&C Act 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 HTML and 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: 061

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: 061'' 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: 061.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–73	1–162	ISO 10651–4 Second edition 2023–03 Lung ventilators—Part 4: Particular requirements for user-powered resuscitators.	Withdrawn and replaced with newer version.
1–105	1–163	ISO 80601–2–72 Second edition 2023–06 Medical electrical equipment—Part 2–72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients.	Withdrawn and replaced with newer version.
1–118	1–164	ISO 5361 Fourth edition 2023–11 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Withdrawn and replaced with newer version.
1–141	1–165	ISO 80601–2–13 Second edition 2022–04 Medical electrical equipment—Part 2–13: Particular requirements for basic safety and essential performance of an anaesthetic workstation.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–94	2–302	ASTM F981–23 Standard Practice for Assessment of Muscle and Bone Tissue Responses to Long-Term Implantable Materials Used in Medical Devices.	Withdrawn and replaced with newer version.
2–237	2–303	ISO 10993–17 Second edition 2023–09 Biological evaluation of medical devices—Part 17: Toxicological risk assessment of medical device constituents.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–105		IEC 60601–2–25 Edition 2.0 2011–10 Medical electrical equipment—Part 2–25: Particular requirements for the basic safety and essential performance of electrocardiographs.	Extent of recognition.
3–126		IEC 60601–2–27 Edition 3.0 2011–03 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)].	Extent of recognition.
3–138	3–189	ASTM F2942–19 Standard Guide for *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–137	4–309	ISO 6877 Third edition 2021–09 Dentistry—Endodontic obturating materials.	Withdrawn and replaced with newer version.
4–151	4–310	ISO 22112 Second edition 2017–08 Dentistry—Artificial teeth for dental prostheses.	Withdrawn and replaced with newer version.
4–188	4–311	ISO 9917–2 Third edition 2017–09 Dentistry—Water-based cements—Part 2: Resin-modified cements.	Withdrawn and replaced with newer version.
4–190	4–312	ANSI/ASA S3.35–2021 American National Standard Method for Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions.	Withdrawn and replaced with newer version.
4–218	4–313	ISO 27020 Second edition 2019–06 Dentistry—Brackets and tubes for use in orthodontics.	Withdrawn and replaced with newer version.
4–221	4–314	ISO 7494–2 Third edition 2022–07 Dentistry—Stationary dental units and dental patient chairs—Part 2: Air, water, suction and wastewater systems.	Withdrawn and replaced with newer version.
4–224	4–315	ISO 24234 Third edition 2021–08 Dentistry—Dental Amalgam	Withdrawn and replaced with newer version.
4–238	4–316	ISO 20127 Second edition 2020–08 Dentistry—Physical properties of powered toothbrushes.	Withdrawn and replaced with newer version.
4–244	4–317	ISO 8325 Third edition 2023–03 Dentistry—Test methods for rotary instruments.	Withdrawn and replaced with newer version.
4–246	4–318	ISO 20749 Second edition 2023–06 Dentistry—Pre-capsulated dental amalgam.	Withdrawn and replaced with newer version.
4–257	4–319	ISO 17730 Second edition 2020–09 Dentistry—Fluoride varnishes	Withdrawn and replaced with newer version.
4–280		ANSI/ADA Standard No. 117–2018 Fluoride varnishes	Withdrawn with transition. See 4–319.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
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)			
6–338	6–497	ASTM D7866–23 Standard Specification for Radiation Attenuating Protective Gloves.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–235	7–318	CLSI EP25 2nd Edition Evaluation of Stability of *In Vitro* Medical Laboratory Test Reagents.	Withdrawn and replaced with newer version.
7–304	7–319	CLSI M23 6th Edition Development of *In Vitro* Susceptibility Test Methods, Breakpoints, and Quality Control Parameters.	Withdrawn and replaced with newer version.
I. Materials			
8–171	8–605	ASTM F1609–23 Standard Specification for Calcium Phosphate Coatings for Implantable Materials.	Withdrawn and replaced with newer version.
8–412	8–606	ASTM F2537–23 Standard Practice for Calibration of Linear Displacement Sensor Systems Used to Measure Micromotion.	Withdrawn and replaced with newer version.
8–437	8–607	ASTM F2082/F2082M–23 Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery.	Withdrawn and replaced with newer version.
8–451	8–608	ASTM F2214–2023 Standard Test Method for In Situ Determination of Network Parameters of Crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE).	Withdrawn and replaced with newer version.
8–475	8–609	ASTM F2026–23 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–483	8–610	ASTM F601–23 Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants.	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			
11–83	.....	ISO 13402 First edition 1995–08–01 Surgical and dental hand instruments—Determination of resistance against autoclaving, corrosion and thermal exposure.	Transferred. See 4–320.
11–276	11–402	ASTM F1798–21 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.	Withdrawn and replaced with newer version.
11–281	.....	ASTM F1672–14 (Reapproved 2019) Standard Specification for Resurfacing Patellar Prosthesis.	Withdrawn with transition. See 11–400.
11–299	.....	ASTM F2068–15 Standard Specification for Femoral Prostheses—Metallic Implants.	Withdrawn with transition. See 11–401.
11–301	.....	ASTM F2091–15 Standard Specification for Acetabular Prostheses	Withdrawn with transition. See 11–401.
11–303	11–403	ASTM F3047M–23 Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-Hard Articulations.	Withdrawn and replaced with newer version.
11–321	11–404	ASTM F2887–23 Standard Specification for Total Elbow Prostheses	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
11–334	11–405	ASTM F1829–23 Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear.	Withdrawn and replaced with newer version.
11–335	11–406	ASTM F3141–23 Standard Guide for Total Knee Replacement Loading Profiles.	Withdrawn and replaced with newer version.
11–341	11–407	ASTM F3140–23 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements.	Withdrawn and replaced with newer version.
11–377	.....	ASTM F2083–21 Standard Specification for Knee Replacement Prosthesis.	Withdrawn with transition. See 11–400.
O. Physical Medicine			
No new entries at this time.			
P. Radiology			
12–348	.....	IEC 60601–2–54 Edition 2.0 2022–09 Medical electrical equipment—Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.	Extent of recognition.
12–349	12–352	NEMA PS 3.1–3.20 2023e Digital Imaging and Communications in Medicine (DICOM) set.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14–141	14–589	ISO 14644–4 Second edition 2022–11 Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up.	Withdrawn and replaced with newer version.
14–379	14–590	ISO 14644–8 Third edition 2022–06 Cleanrooms and associated controlled environments—Part 8: Assessment of air cleanliness by chemical concentration (ACC).	Withdrawn and replaced with newer version.
14–390	14–591	ISO 14644–10 Second edition 2022–05 Cleanrooms and associated controlled environments—Part 10: Assessment of surface cleanliness for chemical contamination.	Withdrawn and replaced with newer version.
14–427	14–592	ISO 13408–1 Third edition 2023–08 Aseptic processing of health care products—Part 1: General requirements.	Withdrawn and replaced with newer version.
14–516	14–593	ASTM F3039–23 Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration.	Withdrawn and replaced with newer version.
14–530	14–594	ISO 11607–1 Second edition 2019–02 [Including ADM1:2023] Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including Amendment 1 (2023)].	Withdrawn and replaced with newer version.
14–531	14–595	ISO 11607–2 Second edition 2019–02 [Including AMD1:2023] Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes [Including Amendment 1 (2023)].	Withdrawn and replaced with newer version.
14–573	14–596	ASTM F88/F88M–23 Standard Test Method for Seal Strength of Flexible Barrier Materials.	Withdrawn and replaced with newer version.
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.

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: 061. 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		
1–166	Gas mixers for medical use—Stand-alone gas mixers.	ISO 11195 Second edition 2018–01.

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

Recognition No.	Title of standard [1]	Reference No. and date
	B. Biocompatibility	
	No new entries at this time.	
	C. Cardiovascular	
3–190	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840–2.	ISO/PAS 7020 First edition 2023–05.
	D. Dental/ENT	
4–320	Surgical and dental and instruments—Determination of resistance against autoclaving, corrosion and thermal exposure.	ISO 13402 First edition 1995–08.
4–321	Dentistry—Intraoral camera	ISO 23450 First edition 2021–03.
4–322	Dentistry—Machinable ceramic blanks	ISO 18675 First edition 2022–05.
4–323	Dentistry—Polymer-based composite machinable blanks	ISO 5139 First edition 2023–05.
4–324	Dentistry—Polymer-based luting materials containing adhesive components	ISO/TS 16506 First edition 2018–03.
	E. General I (QS/RM)	
	No new entries at this time.	
	F. General II (ES/EMC)	
	No new entries at this time.	
	G. GH/GPS	
	No new entries at this time.	
	H. IVD	
7–320	Validation of Assays Performed by Flow Cytometry	CLSI H62 1st Edition.
	I. Materials	
	No new entries at this time.	
	J. Nanotechnology	
18–24	Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles	ASTM E2524–22.
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/G/Urology	
9–150	Copper-bearing contraceptive intrauterine devices—Requirements and tests	ISO 7439 Fourth edition 2023–04.
	M. Ophthalmic	
	No new entries at this time.	
	N. OrthopedicX	
11–400	Non-active surgical implants—Joint replacement implants—Specific requirements for knee-joint replacement implants.	ISO 21536 Third edition 2023–07.
11–401	Non-active surgical implants—Joint replacement implants—Specific requirements for hip-joint replacement implants.	ISO 21535 Third edition 2023–07.
11–408	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion.	ASTM F2777–23.
11–409	Standard Test Methods for Determining the Static Failure Load of Ceramic Knee Femoral Components.	ASTM F3495–23.
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
12–353	American National Standard for Safe Use of Lasers	ANSI Z136.1–2022.

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

Recognition No.	Title of standard [1]	Reference No. and date
Q. Software/Informatics		
13–129	Software and systems engineering—Software testing—Part 1: General concepts	ISO/IEC/IEEE 29119–1 Second edition 2022–01.
13–130	Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2–1: Particular requirements for forensic data logging.	ANSI/AAMI 2700–2–1:2022.
13–131	Standard for medical device security—Security risk management for device manufacturers.	ANSI/AAMI SW96:2023.
R. Sterility		
14–597	Water Quality for Processing Medical Devices	ANSI/AAMI ST108:2023.
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: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04376 Filed 2–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1051]

Clinical Pharmacology Considerations for Antibody-Drug Conjugates; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates,'' which provides recommendations for the development of antibody-drug conjugates (ADCs). Specifically, this guidance addresses the FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs) for ADCs with a cytotoxic small-molecule drug or payload. Currently, there are no final FDA guidances outlining the clinical pharmacology considerations for ADCs. This guidance finalizes the draft guidance of the same title issued on February 8, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on March 1, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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