already-authorized devices.'' What are the economic or supply chain considerations that weigh in favor of or against taking this proposed action? We invite commenters to provide data that we should consider in our analysis.

We tentatively conclude that our proposed action would not have substantial economic and supply chain impacts, especially given that the devices subject to the proposed limitation appear to comprise a very small share of the market. Anzu does not appear in major industry market analyses or rankings. Do commenters agree that economic and supply chain impacts are relatively minor? Could other equipment fill any gaps that may be created by this proposed prohibition? Has the Conditional Approval process provided an adequate source for trusted equipment now or in the future? Would this proposal be cost-effective for the public in terms of obtaining trusted equipment? Would providers' compliance costs decrease as they replace covered equipment with trusted equipment? We strongly encourage commenters to supply data and other specific evidence of economic costs to this prohibition.

We seek comment on any economic benefits that may arise as a result of these prohibitions. Following the initial update to the Covered List, billions of dollars have been raised by domestic UAS producers, creating thousands of United States manufacturing jobs. Billions more have been committed for domestic production of UAS and UAS critical components. These investments include capital from domestic investors as well as foreign investors supporting United States manufacturing. We tentatively conclude that if the proposed prohibitions generated economic harm by noticeably reducing supply, such prohibition would spur investments in domestic production that would generate a countervailing positive economic impact. Do commenters agree? We seek comment on the economic effects of the likely investment in United States production that this proposed prohibition would yield.

Public interest analysis. We tentatively conclude that prohibiting the continued importation and marketing of the previously authorized covered equipment subject to this *Public Notice* is consistent with the public interest because it protects American communications networks from devices specifically determined by an Executive Branch interagency body to ''pose an unacceptable risk to the national security of the United States or the security and safety of United States persons.'' We also tentatively conclude that there are no public interest factors that outweigh our tentative conclusion regarding the proposed ban on import and marketing of this previously authorized covered equipment. We seek comment on this analysis. Do commenters agree that the national security benefits outweigh any negative economic or supply chain factors? Are there any other public interest considerations that weigh in favor or against taking this proposed action? We invite commenters to provide any information that would assist the Commission in its balancing of the need to address the national security risks posed by the continued importation and marketing of previously authorized covered equipment in communications networks with the impact of the proposed prohibitions on government partners, consumers, industry, and the public at large.

Existing authorizations. We clarify that, if this prohibition is adopted, the continued use of previously authorized UAS and UAS critical components that are foreign-produced, as well as communications and video surveillance equipment listed in section 1709 of the FY2025 NDAA and addressed in this *Public Notice,* would remain authorized.

Implementation timeline. We propose that Anzu must cease all importation and marketing activities within 30 days after publication in the **Federal Register**. We seek comment on the proposed timeline from the responsible parties and relevant manufacturers, importers, distributors, retailers, and other interested entities. Specifically, we request comment on implementation considerations including the quantity of devices already imported into the United States and available for—or being held for—marketing or sale; new or recently updated device models that are en route to the United States or pending shipment; and devices subject to executed distribution, marketing, or sales agreements, but have not yet entered the supply chain.

Authority: 47 U.S.C. 151, 154, 229, 301, 302a(b), 303, 1004, 1601–1609; Secure Equipment Act of 2021, Pub. L. 117–55, 135 Stat. 423.

Federal Communications Commission.

Zenji Nakazawa,

Chief, Public Safety and Homeland Security Bureau.

[FR Doc. 2026–17193 Filed 8–21–26; 8:45 am]

BILLING CODE 6712–01–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: 066

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the 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: 066'' (Recognition List Number: 066), 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 August 24, 2026.

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: 066.'' 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: 066.

- 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: 066 is available on the internet at *https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/federal-register-documents.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 066 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: 066'' to Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5612, 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, Rm. 5612, 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 Division of Standards and Conformity Assessment is available at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/division-standards-and-conformity-assessment.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 066

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: 066'' 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 of this notice, 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: 066.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–157	1–203	ISO 10079–1 Fourth edition 2022–03 [Including AMD1:2026] Medical suction equipment—Part 1: Electrically powered suction equipment [Including Amendment 1 (2026)].	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–258	2–313	ISO 10993–1 Sixth edition 2025–11 Biological evaluation of medical devices—Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process.	Withdrawn and replaced with newer version.
2–289	2–314	ISO 10993–12 Fifth edition 2021–01 [Including AMD1:2025] Biological evaluation of medical devices—Part 12: Sample preparation and reference materials [Including AMENDMENT 1 (2025)].	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–173	3–204	ISO 5840–3 Second edition 2021–01 [Including AMD1:2025] Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques [Including: AMENDMENT 1 (2025)].	Withdrawn and replaced with newer version.
3–174	3–205	ISO 5840–1 Second edition 2021–01 [Including AMD1:2025] Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements [Including: AMENDMENT 1 (2025)].	Withdrawn and replaced with newer version.
3–175	3–206	ISO 5840–2 Second edition 2021–01 [Including AMD1:2025] Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes [Including: AMENDMENT 1 (2025)].	Withdrawn and replaced with newer version.
3–189	3–207	ASTM F2942–25 Standard Guide for in vitro Axial, Bending, Torsional, and Compression Durability Testing of Vascular Stents and Vascular Stent-Grafts.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–278	4–368	ISO 4823 Sixth edition 2025–06 Dentistry—Elastomeric impression and bite registration materials.	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
5–135	5–149	ISO 20417 Second edition 2026–03 Medical devices—Information to be supplied by the manufacturer.	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)	
6–389	6–521	IEC 60601–2–2 Edition 6.1 2023–02 CONSOLIDATED VERSION Corrected Version 2025–11 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. Withdrawn and replaced with newer version.
		H. In Vitro Diagnostics (IVD)	
		No new entries at this time.	
		I. Materials	
8–485	8–647	ASTM F3260–25 Standard Test Method for Determining the Flexural Stiffness of Medical Textiles.	Withdrawn and replaced with newer version.
8–520	8–648	ASTM F799–25 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539).	Withdrawn and replaced with newer version.
8–602	8–649	ASTM F2503–26 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
J. Nanotechnology			
18–16	18–25	ISO 21362 First edition 2026–02 Nanotechnologies—Analysis of nano-objects using asymmetrical flow and centrifugal field-flow fractionation.	Withdrawn and replaced with newer version.
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9–133	9–152	ISO 23500–1 Second edition 2024–08 Preparation and quality management of fluids for haemodialysis and related therapies—Part 1: General requirements.	Extent of recognition. Withdrawn and replaced with newer version.
9–134	9–153	ISO 23500–2 Second edition 2024–07 Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies.	Withdrawn and replaced with newer version.
9–135	9–154	ISO 23500–3 Second edition 2024–04 Preparation and quality management of fluids for haemodialysis and related therapies—Part 3: Water for haemodialysis and related therapies.	Withdrawn and replaced with newer version.
9–136	9–155	ISO 23500–4 Second edition 2024–04 Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies.	Extent of recognition. Withdrawn and replaced with newer version.
9–137	9–156	ISO 23500–5 Second edition 2024–04 Preparation and quality management of fluids for haemodialysis and related therapies—Part 5: Quality of dialysis fluid for haemodialysis and related therapies.	Withdrawn and replaced with newer version.
M. Ophthalmic			
No new entries at this time.			
N. Orthopedic			
11–175	.....	ASTM F1582–98 (Reapproved 2016) Standard Terminology Relating to Spinal Implants.	Withdrawn.
11–247	11–441	ASTM F2789–25 Standard Guide for Mechanical and Functional Characterization of Nucleus Devices.	Withdrawn and replaced with newer version.
11–290	.....	ISO 8828 Second edition 2014–11–15 Implants for surgery—Guidance on care and handling of orthopaedic implants.	Withdrawn.
11–319	11–442	ISO 7206–12 Second edition 2025–11 Implants for surgery—Partial and total hip joint prostheses—Part 12: Deformation test method for press-fit acetabular components.	Withdrawn and replaced with newer version.
11–346	11–443	ASTM F2706–25 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
11–353	11–444	ISO 18192–3 Second edition 2025–11 Implants for surgery—Wear of total intervertebral spinal disc prostheses—Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar and cervical prostheses.	Withdrawn and replaced with newer version.
11–371	11–445	ASTM F2009–25 Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses.	Withdrawn and replaced with newer version.
11–398	11–446	ASTM F3574–25 Standard Test Methods for Sacroiliac Joint Fusion Devices.	Withdrawn and replaced with newer version.
O. Physical Medicine			
16–166	16–240	ISO 7176–21 Third edition 2025–04 Wheelchairs—Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	Withdrawn and replaced with newer version.
P. Radiology			
12–51, 12–303.	12–386	IEC 63465 Edition 1.0 2026–01 Calibration and quality control in the use of radionuclide calibrators.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13–106	13–157	IEEE Std. 11073–10207–2017 [Including Cor 1–2025] Standard Health informatics—Point of care medical device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication [Including Corrigendum 1 (2025)].	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
13–142	.....	FIRST CVSS 3.1 Common Vulnerability Scoring System version 3.1	Transition period extended.
R. Sterility			
No new entries at this time.			
S. Tissue Engineering			
15–52	15–70	ASTM F2064–25 Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications.	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: 066. 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		
No new entries at this time.		
C. Cardiovascular		
No new entries at this time.		
D. Dental/ENT		
4–369	Periodontal Curettes, Dental Scalers and Excavators	ANSI/ADA Standard No. 113–2015.
4–370	Casting Investments and Refractory Die Materials	ANSI/ADA Standard No. 126–2015 (R2023).
4–371	Denture Adhesives	ANSI/ADA Standard No. 135–2015 (R2020).
4–372	Dentistry—Dental Duplicating Material	ANSI/ADA Standard No. 141–2013 (R2023).
4–373	Periodontal Probes—Dental Excavators—Discoid Type: General Requirements.	ANSI/ADA Standard No. 170–2019.
4–374	Dental Tweezers	ANSI/ADA Standard No. 195–2021.
4–375	Spoons and Bone Curettes in Dentistry	ANSI/ADA Standard No. 197–2021.
4–376	Dentistry—Dental explorer	ISO 7492 Fourth edition 2019–03.
4–377	Dentistry—Extraction forceps—Part 1: General requirements	ISO 9173–1 Third edition 2016–10.
4–378	Dentistry—Extraction forceps—Part 2: Designation	ISO 9173–2 First edition 2010–05.
4–379	Dentistry—Extraction forceps—Part 3: Design	ISO 9173–3 First edition 2014–05.
4–380	Dentistry—Magnetic attachments	ISO 13017 Second edition 2020–07.
4–381	Dentistry—Dental furnace—Test method for temperature measurement with separate thermocouple.	ISO 13078 First edition 2013–02.
4–382	Dentistry—Dental furnace—Part 2: Test method for evaluation of furnace programme via firing glaze.	ISO 13078–2 First edition 2016–07.
4–383	Dentistry—Dental furnace—Part 3: Test method for the evaluation of high temperature sintering furnace measurement with a separate thermocouple.	ISO 13078–3 First edition 2023–05.
4–384	Periodontal curettes, dental scalers and excavators—Part 1: General requirements.	ISO 13397–1 First edition 1995–12.
4–385	Dentistry—Periodontal curettes, dental scalers and excavators—Part 2: Periodontal curettes of Gr-type [Including AMENDMENT 1 (2012)].	ISO 13397–2 Second edition 2005–06 [Including AMD1:2012].
4–386	Periodontal curettes, dental scalers and excavators—Part 3: Dental scalers—H-type.	ISO 13397–3 First edition 1996–09.
4–387	Dentistry—Periodontal curettes, dental scalers and excavators—Part 5: Jacquette scalers.	ISO 13397–5 First edition 2015–09.
4–388	Dentistry—Duplicating material	ISO 14356 Second edition 2024–10.
4–389	Dentistry—Dental tweezers	ISO 15098 Second edition 2024–07.
4–390	Dentistry—Refractory investment and die material	ISO 15912 Second edition 2016–01.

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

Recognition No.	Title of standard [1]	Reference No. and date
4–391	Dentistry—Minimal dental implant data set for clinical use	ISO 16498 First edition 2013–07.
4–392	Dentistry—Coiled springs for use in orthodontics [Including AMENDMENT 1 (2020)].	ISO 17254 First edition 2016–07 [Including AMD1:2020].
4–393	Dentistry—Reprocessable cartridge syringes for intraligamentary injections.	ISO 21533 Second edition 2018–01.
4–394	Dentistry—Periodontal probes—Part 1: General requirements	ISO 21672–1 First edition 2012–04.
4–395	Dentistry—Materials for dental instruments—Part 1: Stainless steel ..	ISO 21850–1 First edition 2020–04.
4–396	Dentistry—Spoons and bone curettes	ISO 22570 First edition 2020–02.
4–397	Dentistry—Test methods for machining accuracy of computer-aided milling machines.	ISO 23298 First edition 2023–05.
4–398	Dentistry—Excavators	ISO 23940 First edition 2021–04.
4–399	Dentistry—Bonding test between polymer teeth and denture base materials.	ISO TS 19736 First edition 2017–09.
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		
No new entries at this time.		
I. Materials		
8–650	Standard Guide for Content and Format of Test Report Summaries for Medical and Surgical Materials and Device Standards.	ASTM F3766–25.
J. Nanotechnology		
No new entries at this time.		
K. Neurology		
17–23	Medical electrical equipment—Part 2–26: Particular requirements for the basic safety and essential performance of electroencephalographs.	IEC 80601–2–26 First Edition 2024–03 CONSOLIDATED VERSION.
L. OB-Gyn/G/Urology		
No new entries at this time.		
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
No new entries at this time.		
O. Physical Medicine		
16–241	Wheelchairs—Part 31: Lithium-ion battery systems and chargers for powered wheelchairs—Requirements and test methods.	ISO 7176–31 First edition 2023–05.
P. Radiology		
No new entries at this time.		
Q. Software/Informatics		
13–158	Open Mobile Health Data—Representation of Metadata, Sleep, and Physical Activity Measures.	IEEE Std 1752.1–2021.

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.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17229 Filed 8–21–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0528]

Evaluation of Therapeutic Equivalence; 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 titled ''Evaluation of Therapeutic Equivalence.'' This guidance explains FDA's thinking on therapeutic equivalence evaluations and therapeutic equivalence codes (TE codes). FDA's therapeutic equivalence evaluations are listed for multisource prescription drug products approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in the active section of the ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book). These therapeutic equivalence evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. This guidance finalizes the draft guidance of the same title issued in July 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on August 24, 2026.

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 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–2022–D–0528 for ''Evaluation of Therapeutic Equivalence.'' 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.

- 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