Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Unaccompanied [Alien] Child Referral (aka Intakes Restrictive Placement Checklist) (Form P–7)	40	2,394	1.00	95,760
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	220	2	0.25	110
Medical Checklist for Non-Influx Transfers (Form P–9A)	220	8	0.08	141
Medical Checklist for Transfers to Influx Care Facilities (Form P–9B)	220	5	0.17	187
Transfer Request (Form P–10A)—Grantee Case Manager	220	11	0.25	605
Transfer Request (Form P–10A)—Contractor Case Coordinator	275	11	0.17	514
Placement Confirmation (Form P–10B)—Grantee Case Manager	220	11	0.17	411
Placement Confirmation (Form P–10B)—Contractor Case Coordinator	275	11	0.17	514
Transfer Summary and Tracking (Form P–11)	220	11	0.17	411
Bed Configuration Module (Form P–12A)	220	12	0.17	449
Bed Assignment and Capacity Overview Module (Form P–12B)	220	435	0.17	16,269
Program Entity (Form P–12C)	220	12	0.50	1,320
Unaccompanied [Alien] Child Profile (Form P–13)	220	435	0.75	71,775
ORR Transfer Notification—ORR Notification to ICE Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P–14)	220	11	0.17	411
Family Group Entity (Form P–15)	40	75	0.08	240
Influx Transfer Manifest (Form P–16)	3	12	0.33	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	220	52,232	0.50	5,745,520
Estimated Annual Burden Hours Total				5,950,799

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR part 410; *Flores* v. *Reno* Settlement Agreement (No. CV85–4544–RJK (C.D. Cal. 1996)); *Lucas R. et al.* v. *Becerra et al.* Disabilities Settlement Agreement (Case No. CV 18–5741–DMG (PLAx)).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–03282 Filed 2–18–26; 8:45 am]

BILLING CODE 4184–45–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: 065

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: 065'' (Recognition List Number: 065), 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 February 19, 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: 065.'' 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: 065.

- 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: 065 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: 065 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: 065'' 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, 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: 065

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: 065'' 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: 065.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old Recognition No.	Replacement Recognition No.	Title of standard [1]	Change
A. Anesthesiology			
1–106	1–197	ISO 17510 Second Edition 2025–11 Medical devices—Sleep apnoea breathing therapy—Masks and application accessories.	Withdrawn and replaced with newer version.
1–149	1–198	ISO 7376 Third edition 2020–08 [Including AMD1:2025] Anaesthetic and respiratory equipment—Laryngoscopes for tracheal intubation—Amendment 1: Clarification of optical output and illumination requirements [Including Amendment 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
1–151	1–199	ISO 80601–2–70 Third edition 2025–11 Medical electrical equipment—Part 2–70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–141	2–308	ASTM F1984–25 Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials.	Withdrawn and replaced with newer version.
2–155		ASTM F2147–01 (Reapproved 2016) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens.	Withdrawn.
2–189	2–309	ASTM F895–25 Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity.	Withdrawn and replaced with newer version.
2–244	2–310	ASTM F748–25 Standard Practice for Selecting Biological Test Methods for Materials and Devices.	Withdrawn and replaced with newer version.
2–248	2–311	ISO 10993–4 Third edition 2017–04 Amendment 1 2025–1 Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood [including AMENDMENT 1 (2025)].	Withdrawn and replaced with newer version.
2–256	2–312	ASTM F720–24 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–102	3–201	IEC 60601–2–31 Edition 3.0 2020–01 Medical electrical equipment—Part 2–31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source.	Withdrawn and replaced with newer version.
3–115	3–202	IEC 60601–2–34 Edition 4.0 2024–10 Medical electrical equipment—Part 2–34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–153	4–348	ISO 9917–1 Third edition 2025–05 Dentistry—Water-based cements—Part 1: Acid-base cements.	Withdrawn and replaced with newer version.
4–271	4–349	ANSI/ADA Standard No. 34–2025 Dentistry—Cartridge Syringes	Withdrawn and replaced with newer version.
4–275	4–350	ASA/ANSI S3.6–2025 American National Standard Specification for Audiometers.	Withdrawn and replaced with newer version.
4–309	4–351	ISO 6877 Fourth edition 2025–08 Dentistry—Endodontic obturating materials.	Withdrawn and replaced with newer version.
4–312	4–352	ASA/ANSI S3.35–2025 American National Standard Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions.	Withdrawn and replaced with newer version.
4–316	4–353	ISO 20127 Third edition 2025–05 Dentistry—Physical properties of powered toothbrushes.	Withdrawn and replaced with newer version.
4–319	4–354	ISO 17730 Third edition 2025–09 Dentistry—Fluoride varnishes	Withdrawn and replaced with newer version.
4–336	4–355	ISO 18397 Second edition 2025–07 Dentistry—Powered scalers	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
5–108	5–146	ISO 80369–6 Second edition 2025–05 Small bore connectors for liquids and gases in healthcare applications—Part 6: Connectors for neural applications.	Withdrawn and replaced with newer version.
5–121	5–147	ISO 80369–1 Third edition 2025–10 Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements.	Withdrawn and replaced with newer version.
5–134	5–148	ISO 15223–1 Fourth edition 2021–07 Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements [Including Amendment 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
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–43	19–57	IEC 61326–2–6 Edition 4.0 2025–06 Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 2–6: Particular requirements—In vitro diagnostic (IVD) medical equipment.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–384	6–514	ISO 1135–4 Seventh edition 2025–05 Transfusion equipment for medical use—Part 4: Transfusion sets for single use, gravity feed.	Withdrawn and replaced with newer version.
6–411	6–515	ASTM D6499–24 Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products.	Withdrawn and replaced with newer version.
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.	Extent of recognition.
6–448	6–516	ASTM F2407/F2407M–23a Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities.	Withdrawn and replaced with newer version.
6–484	6–517	ASTM F3502–25 Standard Specification for Barrier Face Coverings	Withdrawn and replaced with newer version.
6–491	6–518	ASTM F1670/F1670M–24a Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.	Withdrawn and replaced with newer version.
6–493	6–519	ASTM F2101–25 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.	Withdrawn and replaced with newer version.
6–494	6–520	ASTM F3352/F3352M–23b Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–239	7–346	CLSI EP32 2nd Edition Implementation of Metrological Traceability in Laboratory Medicine.	Withdrawn and replaced with newer version.
7–268	7–347	CLSI EP21 2nd Edition Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures.	Withdrawn and replaced with newer version.
7–284	7–348	CLSI EP37 1st Edition Supplemental Tables for Interference Testing in Clinical Chemistry.	Withdrawn and replaced with newer version.
7–298	7–349	CLSI EP35 1st Edition Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.	Withdrawn and replaced with newer version.
I. Materials			
8–179	8–628	ASTM F754–24 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders.	Withdrawn and replaced with newer version.
8–356	8–629	ASTM F67–24 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).	Withdrawn and replaced with newer version.
8–399	8–630	ASTM F90–24 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605).	Withdrawn and replaced with newer version.
8–400	8–631	ASTM F1854–25 Standard Test Method for Serological Evaluation of Porous Coatings on Medical Implants using Digital Images.	Withdrawn and replaced with newer version.
8–449	8–632	ASTM F1058–25 Standard Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire, Strip, and Bar for Surgical Implant Applications (UNS R30003 and UNS R30008).	Withdrawn and replaced with newer version.
8–455	8–633	ASTM F2902–24 Standard Guide for Assessment of Absorbable Polymeric Implants.	Withdrawn and replaced with newer version.
8–484	8–634	ASTM F2066–23 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150).	Withdrawn and replaced with newer version.
8–498	8–635	ASTM F75–23 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Withdrawn and replaced with newer version.
8–507	8–636	ASTM F688–25 Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	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
8–508	8–637	ASTM F2579–24 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants.	Withdrawn and replaced with newer version.
8–521	8–638	ASTM F2313–24 Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide.	Withdrawn and replaced with newer version.
8–540	8–639	ASTM F1091–25 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605).	Withdrawn and replaced with newer version.
8–544	8–640	ASTM F961–25 Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8–547	8–641	ASTM F629–24 Standard Practice for Radiography of Cast Metallic Surgical Implants.	Withdrawn and replaced with newer version.
8–551	8–642	ASTM F2895–24 Standard Practice for Digital Radiography of Cast Metallic Implants.	Withdrawn and replaced with newer version.
8–574	8–643	ASTM F2820–24 Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–578	8–644	ASTM F2848–25 Standard Specification for Medical-Grade Ultra-High-Molecular-Weight Polyethylene Yarns.	Withdrawn and replaced with newer version.
8–589	8–645	ASTM F1925–24 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for 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			
10–85	10–139	ISO 11980 Fourth edition 2025–06 Ophthalmic optics—Contact lenses and contact lens care products—Requirements and guidance for clinical investigations.	Withdrawn and replaced with newer version.
N. Orthopedic			
11–185	11–423	ASTM F2267–24 Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression.	Withdrawn and replaced with newer version.
11–197	11–424	ASTM F983–24 Standard Practice for Permanent Marking of Orthopaedic Implant Components.	Withdrawn and replaced with newer version.
11–199	11–425	ASTM F565–21 Standard Practice for Care and Handling of Orthopedic Implants and Instruments.	Withdrawn and replaced with newer version.
11–283	11–426	ASTM F2943–25 Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants.	Withdrawn and replaced with newer version.
11–316	11–427	ASTM F1264–24 Standard Specification and Test Methods for Intramedullary Fixation Devices.	Withdrawn and replaced with newer version.
11–322	11–428	ASTM F1541–24 Standard Specification and Test Methods for External Skeletal Fixation Devices.	Withdrawn and replaced with newer version.
11–324	11–429	ASTM F366–24 Standard Specification for Fixation Pins and Wires	Withdrawn and replaced with newer version.
11–325	11–430	ASTM F564–24 Standard Specification and Test Methods for Metallic Bone Staples.	Withdrawn and replaced with newer version.
11–326	11–431	ASTM F384–24 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.	Withdrawn and replaced with newer version.
11–329	11–432	ASTM F2180–24 Standard Specification for Metallic Implantable Strands and Cables.	Withdrawn and replaced with newer version.
11–330	11–433	ASTM F2028–25a Standard Test Methods for Dynamic Evaluation of Glenoid Loosening.	Withdrawn and replaced with newer version.
11–340	11–434	ASTM F3018–25 Standard Guide for Assessment of Hard-on-Hard Articulation in Total Hip Joint Replacement and Resurfacing Hip Joint Replacement.	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
11–369	11–435	ASTM F3292–25 Standard Practice for Inspection of Spinal Implants Undergoing Testing.	Withdrawn and replaced with newer version.
11–374	11–436	ISO 7207–2 Third edition 2025–08 Implants for surgery—Components for partial and total knee joint prostheses—Part 2: Articulating surfaces made of metal, ceramic and plastics materials.	Withdrawn and replaced with newer version.
11–376	11–437	ASTM F2033–25 Standard Specification for Hip Joint Replacement Bearing Surfaces.	Withdrawn and replaced with newer version.
11–378	11–438	ASTM F2502–24 Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants.	Withdrawn and replaced with newer version.
O. Physical Medicine			
16–203	16–237	ASME A18.1:2023 Safety Standard for Platform Lifts and Stairway Chairlifts.	Withdrawn and replaced with newer version.
P. Radiology			
12–361	12–384	ICDM IDMS Version 1.3 May 31, 2025 Information Display Measurements Standard.	Withdrawn and replaced with newer version.
12–363	12–385	NEMA PS 3.1–3.20 2025d Digital Imaging and Communications in Medicine (DICOM) Set.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13–69	13–150	IEEE Std 11073–10472–2023 Health informatics—Device Interoperability—Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor.	Withdrawn and replaced with newer version.
13–92, 13–55	13–151	IEEE Std 11073–10421–2023 Health Informatics—Device Interoperability—Part 10421: Personal Health Device Communication—Device Specialization—Peak expiratory flow monitor (peak flow).	Withdrawn and replaced with newer version.
R. Sterility			
No new entries at this time.			
S. Tissue Engineering			
15–67	15–68	ASTM F2212–25 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.

[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: 065. 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 number and date
A. Anesthesiology		
1–200	Anaesthetic and respiratory equipment—Part 2: Video laryngoscopes	ISO 7376–2 First edition 2025–09.
1–201	Lung ventilators and related equipment—Vocabulary and semantics—Part 2: High frequency and jet ventilation.	ISO 19223–2 First edition 2025–04.
1–202	Lung ventilators and related equipment—Vocabulary and semantics—Part 3: Respiratory care.	ISO 19223–3 First edition 2025–09.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3–203	Medical electrical equipment—Part 2–49: Particular requirements for the basic safety and essential performance of multifunction patient monitors.	IEC 80601–2–49 Edition 1.1 2024–09 CONSOLIDATED VERSION.

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

Recognition No.	Title of standard [1]	Reference number and date
	D. Dental/ENT	
4–356	Dentistry—Orthodontic Wires	ANSI/ADA Standard No. 32–2024.
4–357	Double-Pointed, Parenteral, Single Use Needles for Dentistry	ANSI/ADA Standard No. 54–1986 (R2024).
4–358	Endodontics Instruments—Enlargers	ANSI/ADA Standard No. 95–2020.
4–359	Dentistry—Coiled Springs for Use in Orthodontics	ANSI/ADA Standard No. 159–2024.
4–360	Dentistry—Endodontic instruments—Part 1: General requirements	ISO 3630–1 Third edition 2019–08.
4–361	Dentistry—Endodontic instruments—Part 2: Enlargers	ISO 3630–2 Fourth edition 2023–02.
4–362	Dentistry—Endodontic instruments—Part 3: Compactors	ISO 3630–3 Third edition 2021–06 Corrected version 2023–05.
4–363	Dentistry—Endodontic instruments—Part 5: Shaping and cleaning instruments	ISO 3630–5 Second edition 2020–08.
4–364	Dentistry—Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials.	ISO 3990 First edition 2023–07.
4–365	Dentistry—Gypsum products	ISO 6873 Third edition 2013–04.
4–366	Dentistry—Endodontic absorbent points	ISO 7551 Second edition 2023–05.
4–367	Dentistry—Cartridge syringes	ISO 9997 Third edition 2020–01.
	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	
7–351	Determining Allowable Total Error Goals and Limits for Quantitative Medical Laboratory Measurement Procedures.	CLSI EP46 1st Edition.
	I. Materials	
8–646	Standard Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Medical Applications.	ASTM F624–25.
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/G/Urology	
	No new entries at this time.	
	M. Ophthalmic	
10–140	American National Standard for Ophthalmics—Prescription Ophthalmic Lenses—Recommendations.	ANSI Z80.1–2020.
10–141	Ophthalmic optics—Contact lenses and contact lens care products—Labelling [Including Amendment 1 (2020)].	ISO 11978 Third edition 2017–08 [Including AMD1:2020].
	N. Orthopedic	
11–439	Standard Test Methods for Metallic Bone Plates Used in Small Bone Fracture Fixation.	ASTM F3437–23.
11–440	Standard Test Method for Hip Simulator Wear Testing of Metal-on-Polyethylene Articulations Under Adverse Conditions Using Third-Body Particles.	ASTM F3738–25.
	O. Physical Medicine	
16–238	Assistive products for walking manipulated by both arms—Requirements and test methods Part 1: Walking frames.	ISO 11199–1 Second edition 2021–05.
16–239	Assistive products for walking manipulated by both arms—Requirements and test methods Part 2: Rollators [Including Amendment 1 (2024)].	ISO 11199–2 Third edition 2021–07 [Including AMD1:2024].

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

Recognition No.	Title of standard [1]	Reference number and date
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
13–152	Health informatics—Accelerating safe, effective and secure remote connected care and mobile health through standards-based interoperability solutions addressing gaps revealed by pandemics.	ISO TS 5615:2025.
13–153	Cybersecurity Consideration Unique to Machine-Learning Enabled Medical Devices.	AAMI CR515.
13–154	Health informatics—Device Interoperability—Part 10429: Personal Health Device Communication—Device Specialization—Spirometry.	IEEE Std 11073–10429–2022.
13–155	Health informatics—Device Interoperability Part 10442: Personal health device communication—Device specialization—Strength fitness equipment.	IEEE Std 11073–10442–2023.
13–156	Health Informatics—Device Interoperability—Part 10471: Personal Health Device Communication—Device Specialization—Independent Living Activity Hub.	IEEE Std 11073–10471–2023.
	R. Sterility	
14–612	Bacterial Endotoxins Test Using Recombinant Reagents	USP–NF <86> M16015_02_01.
	S. Tissue Engineering	
15–69	Standard Practice for Automated Colony Forming Unit (CFU) Assays—Image Acquisition and Analysis Method for Enumerating and Characterizing Cells and Colonies in Culture.	ASTM F2944–20.

[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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0342]

Sherri Insprucker: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Sherri Insprucker for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Insprucker was convicted of one felony count under Federal law for conspiracy to introduce a misbranded drug in interstate commerce with the intent to defraud and mislead. The factual basis supporting Ms. Insprucker's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Insprucker was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of June 16, 2025 (30 days after receipt of the notice), Ms. Insprucker had not responded. Ms. Insprucker's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable February 19, 2026.

ADDRESSES: Any application by Ms. Insprucker for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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