addition, ORR has written an instructional letter for the Mental Health Assessment Form to explain the purpose of the form and provide general guidance on completion to healthcare providers.

Respondents: Mental health professionals (psychiatrists, psychiatric nurse practitioners or physician's assistants, licensed psychologist or any other community based licensed mental health provider (*e.g.,* social worker)), care provider program staff.

Annual Burden Estimates

ESTIMATED OPPORTUNITY TIME FOR RESPONDENTS

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Mental health professionals	500	6.8	0.18	612
Public Health Investigation Form: Active TB.	Care provider program staff	500	1	0.08	400
Public Health Investigation Form: Non-TB Illness.		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,012.

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Care provider program staff	500	6.8	0.21	714
Public Health Investigation Form: Active TB		500	1	0.08	400
Public Health Investigation Form: Non-TB Illness		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,114.

Authority: 6 U.S.C. 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16840 Filed 8–4–23; 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: 060

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: 060'' (Recognition List Number: 060), 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 7, 2023.

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: 060.'' 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: 060.

- 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: 060 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: 060 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: 060'' to Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580. 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: Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301–796–6580, *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: 060

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: 060'' 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: 060.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–127	1–161	ISO 16628 Second edition 2022–06 Anaesthetic and respiratory equipment—Tracheobronchial tubes.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–213	2–299	ASTM F1904–23 Standard Guide for Testing the Biological Responses to Medical Device Particulate Debris and Degradation Products in vivo.	Withdrawn and replaced with newer version.
2–222	2–300	ISO 10993–2 Third edition 2022–11 Biological evaluation of medical devices—Part 2: Animal welfare requirements.	Withdrawn and replaced with newer version.
2–227	2–301	ASTM F1983–23 Standard Practice for Assessment of Selected Tissue Effects of Absorbable Biomaterials for Implant Applications.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–87	3–184	ASTM F2477–23 Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–86		ANSI/ADA Standard No. 38–2000 (R2015) Metal-Ceramic Dental Restorative Systems.	Withdrawn.
4–139		ANSI/ADA Standard No. 48–2004 (R2015) Visible Light Curing Units	Withdrawn.
4–181	4–298	ISO 4049 Fifth edition 2019–05 Dentistry—Polymer-based restorative materials.	Withdrawn and replaced with newer version.
4–198	4–299	ISO 3107 Fifth edition 2022–09 Dentistry—Zinc oxide-eugenol cements and non-eugenol zinc oxide cements.	Withdrawn and replaced with newer version.
4–227	4–300	ISO 22674 Third edition 2022–08 Dentistry—Metallic materials for fixed and removable restorations and appliances.	Withdrawn and replaced with newer version.
4–231		ISO/TS 11405 Third edition 2015–02–01 Dentistry—Testing of adhesion to tooth structure.	Withdrawn.
4–240	4–301	ISO 21563 Second edition 2021–08 Dentistry—Hydrocolloid impression materials.	Withdrawn and replaced with newer version.
4–248	4–302	ISO 10477 Fourth edition 2020–10 Dentistry—Polymer-based crown and veneering materials.	Withdrawn and replaced with newer version.
4–249		ANSI/ADA Standard No. 19–2018 Elastometric Impression Materials	Withdrawn.
4–253		ANSI/ADA Standard No. 27–2016 Polymer-based Restorative Materials	Withdrawn. See 4–298.
4–264	4–303	ISO 9333 Third edition 2022–08 Dentistry—Brazing materials	Withdrawn and replaced with newer version.
4–267	4–304	ISO 21606 Second edition 2022–08 Dentistry—Elastomeric auxiliaries for use in orthodontics.	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
		No new entries at this time.	
		F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–34		IEC 61010–1 Edition 3.1 2017–01 CONSOLIDATED VERSION Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements [Including: Corrigendum 1 (2019)].	Recognition restored.
		G. General Hospital/General Plastic Surgery (GH/GPS)	
6–253	6–486	ISO 10535 Third Edition 2021–10 Assistive products—Hoists for the transfer of persons—Requirements and test methods.	Withdrawn and replaced with newer version.
6–296	6–487	AAMI PB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.	Withdrawn and replaced with newer version.
6–306	6–488	ASTM F1671/F1671M–22 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.	Withdrawn and replaced with newer version.
6–321	6–489	IEC 60601–2–52 Edition 1.1 2015–03 CONSOLIDATED VERSION Medical electrical equipment—Part 2–52: Particular requirements for the basic safety and essential performance of medical beds.	Withdrawn and replaced with newer version.
6–357	6–490	ISO 10555–6 First edition 2015–04–15 Intravascular catheters—Sterile and single-use catheters—Part 6: Subcutaneous implanted ports [Including Amendment 1 (2019)].	Withdrawn and replaced with newer version.
6–402	6–491	ASTM F1670/F1670M–17a Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.	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
6–425	6–492	ASTM F2100–23 Standard Specification for Performance of Materials Used in Medical Face Masks.	Withdrawn and replaced with newer version.
6–427	6–493	ASTM F2101–23 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.
6–474	6–494	ASTM F3352/F3352M–23a Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–152	7–315	CLSI EP12 3rd Edition Evaluation of Qualitative, Binary Output Examination Performance.	Withdrawn and replaced with newer version.
7–244	7–316	CLSI NBS01 7th Edition Dried Blood Spot Specimen Collection for Newborn Screening.	Withdrawn and replaced with newer version.
7–308	7–317	CLSI M100, 33rd Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
I. Materials			
8–200	8–597	ASTM F2003–02(2022) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation in Air.	Withdrawn and replaced with newer version.
8–441	8–598	ASTM F3109–22 Standard Practice for Verification of Multi-Axis Force Measuring Platforms.	Withdrawn and replaced with newer version.
8–453	8–599	ASTM F1295–22 Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700).	Withdrawn and replaced with newer version.
8–467	8–600	ASTM F1978–22 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser.	Withdrawn and replaced with newer version.
8–506	8–601	ASTM F2516–22 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials.	Withdrawn and replaced with newer version.
8–528	8–602	ASTM F2503–23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.
8–555	8–603	ASTM F1472–23 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Withdrawn and replaced with newer version.
J. Nanotechnology			
18–15	18–23	ASTM E3025–22 Standard Guide for Tiered Approach to Detection and Characterization of Silver Nanomaterials in Textiles.	Withdrawn and replaced with newer version.
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9–67	9–145	ASTM D7661–18 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.	Withdrawn and replaced with newer version.
9–94	9–146	ISO 8600–4 Third Edition 2023–01 Endoscopes—Medical endoscopes and endotherapy devices—Part 4: Determination of maximum width of insertion portion.	Withdrawn and replaced with newer version.
9–125	9–147	ISO/CIE 11664–2 First edition 2022–08 Colorimetry—Part 2: CIE standard illuminants.	Withdrawn and replaced with newer version.
9–128	9–148	ISO/CIE 11664–6 Second edition 2022–08 Colorimetry—Part 6: CIEDE2000 Colour-difference formula.	Withdrawn and replaced with newer version.
9–143	.....	ISO 20696 First edition 2018–06 Corrected version 2019–12 Sterile urethral catheters for single use.	Extent of recognition.
M. Ophthalmic			
No new entries at this time.			
N. Orthopedic			
11–294	11–399	ASTM F1357–23 Standard Specification for Articulating Total Wrist Implants.	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
O. Physical Medicine			
16–165	16–234	ISO 7176–14 Third Edition 2022 Wheelchairs—Part 14 Power and control systems for electrically powered wheelchairs and scooters—Requirements and test methods.	Withdrawn and replaced with newer version.
16–194	16–235	ISO 7176–25 Second Edition 2022 Wheelchairs—Part 25: Lead-acid batteries and chargers for powered wheelchairs—Requirements and test methods.	Withdrawn and replaced with newer version.
16–201	16–236	ISO 7176–19 Third Edition 2022 Wheelchairs—Part 19: Wheeled mobility devices for use as seats in motor vehicles.	Withdrawn and replaced with newer version.
P. Radiology			
12–6	12–350	IEC 60806 Edition 2.0 2022–11 Determination of the maximum symmetrical radiation field of X-ray tube assemblies and X-ray source assemblies for medical diagnosis.	Withdrawn and replaced with newer version.
12–347	.....	IEC 60601–2–33 Edition 4.0 2022–08 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Transition period extended.
12–329	12–351	IEC 60601–2–43 Edition 3.0 2022–12 Medical electrical equipment—Part 2–43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
No new entries at this time.			
R. Sterility			
14–169	14–584	ASTM F2391–22 Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Withdrawn and replaced with newer version.
14–456	14–585	ISO/TS 16775 Second edition 2021–11 Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607–1 and ISO 11607–2.	Withdrawn and replaced with newer version.
14–575	.....	ASTM F1980–21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Transition period extended.
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: 060. 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		
3–185	Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging.	ANSI/AAMI PC76:2021.
3–186	Implants for surgery—Active implantable medical devices—Part 2: Cardiac pacemakers.	ISO 14708–2 Third edition 2019–09.
3–187	Implants for surgery—Active implantable medical devices—Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators).	ISO 14708–6 Second edition 2019–09.

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

Recognition No.	Title of standard [1]	Reference No. and date
3–188	Non-invasive sphygmomanometers—Part 3: Clinical investigation of continuous automated measurement type.	ISO 81060–3 First edition 2022–12.
	D. Dental/ENT	
4–305	Dentistry—Central suction source equipment	ISO 10637 Second edition 2018–05.
4–306	Dentistry—Compressed air source equipment	ISO 22052 First edition 2020–06.
4–307	Dentistry—General requirements for instruments and related accessories used in dental implant placement and treatment.	ISO 13504 First edition 2012–07.
4–308	Implants for surgery—Active implantable medical devices—Part 7: Particular requirements for cochlear and auditory brainstem implant systems.	ISO 14708–7 Second edition 2019–12 (Corrected version 2020–05).
	E. General I (QS/RM)	
	No new entries at this time.	
	F. General II (ES/EMC)	
19–49	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.	IEC 60601–1 Edition 3.2 2020–08 CONSOLIDATED VERSION.
	G. GH/GPS	
6–495	Catheter systems for neuraxial application—Sterile and single-use catheters and accessories.	ISO 20698 First Edition 2018–07.
6–496	Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact.	ASTM F739–20.
	H. IVD	
	No new entries at this time.	
	I. Materials	
8–604	Standard Specification for Wrought Seamless or Welded and Drawn 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673).	ASTM F2257–22.
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/G/Urology	
9–149	Medical electrical equipment—Part 2–39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment.	IEC 60601–2–39 Edition 3.0 2018–04.

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

Recognition No.	Title of standard [1]	Reference No. and date
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
	No new entries at this time.	
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
	No new entries at this time.	
	R. Sterility	
14–586	Sterilization of health care products—Low temperature vaporized hydrogen peroxide—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 22441 First edition 2022–08.
14–587	Guidance on transferring health care products between radiation sterilization sources	AAMI TIR104:2022.
14–588	Compatibility of materials subjected to sterilization	AAMI TIR17:2017/(R)2020.
	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: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16770 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3032]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous Oxide (N_2O); Carisoprodol; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is inviting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of eight drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Either electronic or written comments must be submitted by August 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.