classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629), which broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide reasonable assurance of the safety and effectiveness of such devices.

In December 2000, Congress enacted Public Law 106–554, which directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases * * *.'' In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA expects approximately five new manufacturers or repackagers to enter the market yearly and to collectively have a third-party disclosure burden of 60 hours. The number of respondents cited in table 1 of this document is based on FDA's database of premarket submissions and the electronic registration and listing database. The average burden per disclosure was derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

The collection of information under 21 CFR 801.437 does not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

In the **Federal Register** of October 15, 2014 (79 FR 61874), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300	5	1	5	12	60

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01403 Filed 1–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 038

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: 038'' (Recognition List Number: 038), 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 concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 038 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 038 modifications and other standards related information.

Submit written requests for a single copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 038'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.

Submit electronic comments on this document to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring,

MD 20993, 301–796–6287, *standards@cdrh.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 038

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term ''Recognition List Number: 038'' to identify these 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 the initial addition of standards not previously recognized by FDA.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesia	
1–57		ASTM F1101–90 (Reapproved 2003) Standard Specification for Ventilators Intended for Use During Anesthesia.	Withdrawn.
1–69		ASTM F1464–93 (Reapproved 2005) Standard Specification for Oxygen Concentrators for Domiciliary Use.	Withdrawn.
1–70		ASTM F1246–91 (Reapproved 2005) Standard Specification for Electrically Powered Home Care Ventilators—Part 1: Positive-Pressure Ventilators and Ventilator Circuits.	Withdrawn.
1–94		ISO 8359 Second edition 1996–12–15, Oxygen concentrators for medical use—safety requirements [including amendment 1 (2012)].	Withdrawn. See 1–102.
		B. Biocompatibility	
2–143	2–213	ASTM F1904–14 Standard Practice for the Biological Responses to Particles in vivo.	Withdrawn and replaced with newer version.
2–144	2–214	ASTM F619–14 Standard Practice for Extraction of Medical Plastics.	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–88		ASTM F2514–08 (Reapproved 2014) Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading.	Reaffirmation.
3–123		IEC 80601–2–30 Edition 1.1 2013–07, Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	Extent of recognition and Process impacted.
		D. Dental/ENT	
4–117		ANSI/ADA Specification No. 12: 2002 (Reaffirmed 2008) Denture base polymers.	Withdrawn.
4–134	4–213	ISO 7494–1 Second edition 2011–08–15 Dentistry—Dental units—Part 1: General requirements and test methods.	Withdrawn and replaced with newer version.
4–135	4–214	ISO 10139–1 Second edition 2005–02–15, Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use [Including: Technical Corrigendum 1 (2006)].	Withdrawn and replaced with newer version including technical corrigendum.
4–136		ASTM F2504–05 (Reapproved 2014) Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices.	Reaffirmation.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
4–143	4–215	ANSI/ADA Standard No. 96: 2012 Dental Water-based Cements	Withdrawn and replaced with newer version.
4–159	4–216	ANSI/IEEE ANSI C63.19–2011 American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids.	Withdrawn and replaced with newer version.
4–170	4–217	ANSI/ASA S3.36–2012 American National Standard Specification for a Manikin for Simulated in-situ Airborne Acoustic Measurements.	Withdrawn and replaced with newer version.
4–183		ANSI/ASA S3.2–2009 (Reaffirmed 2014) American National Standard Method for Measuring the Intelligibility of Speech over Communication Systems.	Reaffirmation.
4–185		ANSI/ASA S3.45–2009 (Reaffirmed 2014) American National Standard Procedures for Testing Basic Vestibular Function.	Reaffirmation.
		E. General I (Quality Systems/Risk Management (QS/RM))	
5–48		ANSI/ASQ Z1.9–2003 (R2013) Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming.	Reaffirmation.
5–57		ANSI/AAMI HE75:2009/(R)2013 Human factors engineering—Design of medical devices.	Reaffirmation.
5–62		ANSI/ASQ Z1.4–2003 (R2013) Sampling Procedures and Tables for Inspection by Attributes.	Reaffirmation.
		F. General Hospital/General Plastic Surgery (GH/GPS)	
6–199	6–335	ASTM F2101–14 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.
6–217		ASTM F1670/F1670M–08 (Reapproved 2014) epsiv;1 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.	Reaffirmation.
6–228	6–336	IEC 60601–2–2 Edition 5.0 2009–02 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 [Including: Technical Corrigendum 1 (2014)].	Withdrawn and replaced with newer version including technical corrigendum.
6–231	6–337	ANSI/AAMI/IEC 60601–2–20:2009 Medical Electrical Equipment—Part 2–20: Particular Requirements for the Basic Safety and Essential Performance of Infant Transport Incubators [Including: Erratum (2012)].	Withdrawn and replaced with newer version including erratum.
		G. In Vitro Diagnostics (IVD)	
7–84		CEN 13640, Stability Testing of In Vitro Diagnostic Reagents	Withdrawn.
7–162		CLSI POCT14–A (Formerly H49–A) Point-Of-Care Monitoring of Anticoagulation Therapy; Approved Guideline.	Withdrawn duplicate. See 7–112.
7–184	7–250	CLSI M40–A2 Quality Control of Microbiological Transport Systems; Approved Standard—Second Edition.	Withdrawn and replaced with newer version.
		H. Materials	
8–111	8–380	ASTM F1160–14 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings.	Withdrawn and replaced with newer version.
8–124	8–381	ASTM F2052–14 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.
8–171		ASTM F1609–08 (Reapproved 2014) Standard Specification for Calcium Phosphate Coatings for Implantable Materials.	Reaffirmation.
8–198	8–382	ASTM F2102–13 Standard Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants.	Withdrawn and replaced with newer version.
8–207	8–383	ASTM F1926/F1926M–14 Standard Test Method for Dissolution Testing of Calcium Phosphate Granules, Fabricated Forms, and Coatings.	Withdrawn and replaced with newer version.
8–340	8–384	ASTM F2026–14 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–357	8–385	ASTM F648–14 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical 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
I. OB–GYN/Gastroenterology/Urology			
9–6	9–95	IEC 60601–2–36 Edition 2.0 2014–04 Medical electrical equipment—Part 2–36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy.	Withdrawn and replaced with newer version.
9–45		ASTM F2528 – 06 (Reapproved 2014) Standard Test Methods for Enteral Feeding Devices with a Retention Balloon.	Reaffirmation.
9–62	9–96	IEC 60601–2–2 Edition 5.0 2009–02 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 [Including: Technical Corrigendum 1 (2014)].	Withdrawn and replaced with newer version including technical corrigendum.
9–74	9–97	ISO 13958 Third edition 2014–04–01 Concentrates for haemodialysis and related therapies.	Withdrawn and replaced with newer version.
9–76	9–98	ISO 13959 Third edition 2014–04–01 Water for haemodialysis and related therapies.	Withdrawn and replaced with newer version.
9–77	9–99	ISO 23500 Second edition 2014–04–01 Guidance for the preparation and quality management of fluids for haemodialysis and related therapies.	Withdrawn and replaced with newer version.
9–78	9–100	ISO 11663 Second edition 2014–04–01 Quality of dialysis fluid for haemodialysis and related therapies.	Withdrawn and replaced with a newer version.
9–79	9–101	ISO 26722 Second edition 2014–04–01 Water treatment equipment for haemodialysis applications and related therapies.	Withdrawn and replaced with a newer version.
9–82	9–102	ISO 4074 Second edition 2014–08–15 Natural rubber latex male condoms—Requirements and test methods.	Withdrawn and replaced with newer version.
J. Ophthalmic			
10–49	10–90	ISO 11979–9 First edition 2006–09–01 Ophthalmic implants—Intraocular lenses—Part 9: Multifocal intraocular lenses [Including: Amendment 1(2014)].	Withdrawn and replaced with newer version including amendment.
10–50	10–91	ISO 11979–10 First edition 2006–08–15 Ophthalmic implants—Intraocular lenses—Part 10: Phakic intraocular lenses [Including: Amendment 1 (2014)].	Withdrawn and replaced with newer version including amendment.
10–80		ISO 18369–2 Second edition 2012–12–01 Ophthalmic optics—Contact lenses—Part 2: Tolerances.	Extent of recognition and relevant guidance.
K. Orthopedic			
11–196	11–281	ASTM F1672–14 Standard Specification for Resurfacing Patellar Prosthesis.	Withdrawn and replaced newer version.
11–213	11–282	ASTM F1223–14 Standard Test Method for Determination of Total Knee Replacement Constraint.	Withdrawn and replaced with newer version.
11–260	11–283	ASTM F2943–14 Standard Guide for Presentation of End User Labeling Information for Musculoskeletal Implants.	Withdrawn and replaced with newer version.
11–263	11–284	ASTM F2028–14 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.	Withdrawn and replaced with newer version.
L. Physical Medicine			
16–189	16–193	ASME A18.1–2014 Safety Standard for Platform Lifts and Stairway Chairlifts.	Withdrawn and replaced with newer version.
M. Radiology			
12–181	12–284	NEMA NU 1–2012 Performance Measurements of Gamma Cameras.	Withdrawn and replaced with newer version.
12–206	12–285	IEC 60601–2–1 Edition 3.1 2014–07 Medical electrical equipment—Part 2–1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV.	Withdrawn and replaced with newer version.
12–230		NEMA XR 24–2008 (R2014) Primary User Controls for Interventional Angiography X-Ray Equipment.	Reaffirmation.
N. Sterility			
14–139		ISO 14644–1 First edition 1999–05–01 Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness.	Relevant guidance.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–140		ISO 14644–2 First edition 2000–09–15 Cleanrooms and associated controlled environments—Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644–1.	Relevant guidance.
14–141		ISO 14644–4 First edition 2001–04–01 Cleanrooms and associated controlled environments—Part 4: Design, construction and start-up.	Relevant guidance.
14–165		ISO 14644–5 First edition 2004–08–15 Cleanrooms and associated controlled environments—Part 5: Operations.	Relevant guidance.
14–166		ISO 14644–7 First edition 2004–10–01 Cleanrooms and associated controlled environments—Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments).	Relevant guidance.
14–193		ANSI/AAMI/ISO 11607–1:2006/(R)2010, Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems.	Relevant guidance.
14–194		ANSI/AAMI/ISO 11607–2:2006/(R)2010, Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes.	Relevant guidance.
14–238		AAMI/ANSI/ISO 11140–5:2007/(R)2012, Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.	Relevant guidance.
14–242		ISO 14644–3 First edition 2005–12–15 Cleanrooms and associated controlled environments—Part 3: Test methods.	Relevant guidance.
14–243		ISO 14644–6 First edition Cleanrooms and associated controlled environments—Part 6: Vocabulary.	Relevant guidance.
14–274		ANSI/AAMI/ISO 15882:2008/(R)2013, Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results.	Reaffirmation.
14–299	14–453	ASTM F2097–14 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Withdrawn and replaced with newer version.
14–355	14–454	ISO 11607–1 First edition 2006–04–15 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)].	Withdrawn and replaced with newer version including amendment.
14–356	14–455	ISO 11607–2 First edition 2006–04–15 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)].	Withdrawn and replaced with newer version including amendment.
14–379		ISO 14644–8 Second edition 2013–02–15 Cleanrooms and associated controlled environments—Part 8: Classification of air cleanliness by chemical concentration (ACC).	Relevant guidance.
14–389		ISO 14644–9 First edition 2012–08–15 Cleanrooms and associated controlled environments—Part 9: Classification of surface cleanliness by particle concentration.	Relevant guidance.
14–390		ISO 14644–10 First edition 2013–03–01 Cleanrooms and associated controlled environments—Part 10: Classification of surface cleanliness by chemical concentration.	Relevant guidance.

[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: 038.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
	A. Anesthesia	
1–102	Medical electrical equipment—Part 2–69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.	ISO 80601–2–69 First edition 2014–07–15.
	B. Cardiovascular	
3–133	International Standard-Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques.	ISO 5840–3 First edition 2013–03–01.

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

Recognition No.	Title of standard [1]	Reference No. and date
C. Dental/Ear, Nose, and Throat		
4–218	International Standard–Dentistry—Brackets and tubes for use in orthodontics.	ISO 27020 First edition 2010–12–15.
4–219	International Standard–Dentistry–Adhesive–Notched Edge Sheer Bond Strength Test.	ISO 29022 First edition 2013–06–01.
D. General Hospital/General Plastic Surgery		
6–338	Standard Specification for Radiation Attenuating Protective Gloves.	ASTM D7866–14a.
6–339	Standard Consumer Safety Specification for Full-Size Baby Cribs.	ASTM F1169–13.
6–340	Standard Consumer Safety Performance Specification for Commercial Cribs.	ASTM F2710–13.
E. Nanotechnology		
18–3	Technical Specification—Surface characterization of gold nanoparticles for nanomaterial specific toxicity screening: FT–IR method.	ISO/TS 14101 First edition 2012–11–01.
F. Neurology		
17–13	IEEE Recommended Practice for Neurofeedback Systems ...	IEEE Std 2010–2012.
G. Ophthalmics		
10–92	American National Standard for Ophthalmics-Contact Lenses—Standard Terminology, Tolerances, Measurements and Physicochemical Properties.	ANSI Z80.20–2010 (Revision of ANSI Z80.20–2004) 12/06/2010.
10–93	American National Standard for Ophthalmics-Implantable Glaucoma Devices.	ANSI Z80.27–2014 (revision of ANSI Z80.27–2001 (R2011)) 01/27/2014.
H. Orthopedic		
11–285	Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging.	ASTM F2978–13.
11–286	Guide For the Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Prostheses.	ASTM F2979–14.
I. Radiology		
12–286	X-ray Equipment for Interventional Procedures—User Quality Control Mode.	NEMA XR–27–2013 with Amendment 1.
12–287	Supplemental Requirements for User Information and System Function Related to Dose in CT.	NEMA XR 28–2013.
12–288	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI).	NEMA MS 9–2008.
J. Software/Informatics		
13–70	Application of risk management for IT-networks incorporating medical devices—Part 2–5: Application guidance—Guidance on distributed alarm systems.	IEC TR 80001–2–5 2014.
13–71	Logical Observation Identifiers Names and Codes (LOINC) ...	LOINC 2.48 2014–06–27.
13–72	Health informatics—Personal health device communication, Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).	IEEE Std 11073–10425–2014.
K. Sterility		
14–456	Packaging for terminally sterilized medical devices—Guidance on the application of ISO 11607–1 and ISO 11607–2.	ISO/TS 16775 First edition 2014–05–15.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. 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. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

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 *standards@cdrh.fda.gov.* To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of Recognized Standards, Recognition List Number: 038'' will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* 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: 038. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: January 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01420 Filed 1–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0198]

Current Good Manufacturing Practice Requirements for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Current Good Manufacturing Practice Requirements for Combination Products.'' The guidance describes and explains the final rule on current good manufacturing practice (CGMP) requirements for combination products, including presenting general considerations for CGMP compliance as well as analysis of hypothetical scenarios.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 30, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Current Good Manufacturing Practice Requirements for Combination Products'' to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Current Good Manufacturing Practice Requirements for Combination Products.'' The guidance provides background on combination products, including an overview of the final rule on CGMP requirements for combination products (78 FR 4307, January 22, 2013) (21 CFR part 4) and the role of the lead center and other Agency components with respect to combination product CGMP issues. The guidance addresses general considerations for CGMP requirements for combination products and the purpose and content of specific CGMP provisions addressed in part 4. The guidance also contains hypothetical scenarios intended to clarify how to