Drug Court Team Questionnaire

This questionnaire will be administered to key drug court personnel (*e.g.,* judge, drug court manager and treatment provider) during the three annual site visits to the drug court. This instrument consists of 15 open-ended questions, and will ask respondents about their role and involvement in the drug court process, perceptions of drug courts, and the role of treatment and coercion in drug courts (subject to OMB approval).

Drug Court Client Focus Group Questions for Guided Discussion

Focus groups will be conducted during the annual site visits to each drug court. During the focus groups, drug court clients will be asked 12 open-ended questions about their experiences in the drug court program and current efforts towards recovery. Drug court participants will be involved in focus groups on 1 to 3 occasions.

Procedural Justice Questionnaire

This instrument contains 13 items and asks drug court clients about their perceptions regarding fair treatment by the judge and drug court team during the drug court process. It is hypothesized that participants who perceive the judge and drug court team as fair will be more compliant with the drug court program, more likely to graduate, and have better substance use and criminal behavior outcomes (*e.g.,* reduced substance use, fewer arrests). This questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview.

Correctional Mental Health Screener for Women

A mental health screener for women (CMHS–W) will be administered to gather data on drug court participants' mental health. Many drug court clients have co-occurring disorders (*i.e.,* substance use and mental health disorders). The information gathered during this portion of the in-person drug court client interviews will provide a post-discharge indicator of mental health status and will be used as a moderator variable when assessing client outcomes such as drug use and arrest. This questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview. The CMHS–W contains eight questions, and six items are common between the men and women's versions of the instrument.

Correctional Mental Health Screener for Men

A mental health screener for men (CMHS–M) will be administered to gather data on drug court participants' mental health. Many drug court clients have co-occurring disorders (*i.e.,* substance use and mental health disorders). The information gathered during this portion of the in-person drug court client interviews will provide a post-discharge indicator of mental health status and will be used as a moderator variable when assessing client outcomes such as drug use and arrest. This questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview. The CMHS–M contains twelve questions and the two instruments have six items in common.

Treatment Satisfaction Index

The Treatment Satisfaction Index will ask drug court participants about their satisfaction with treatment received during the drug court program. This 19-item questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview.

The estimated response burden for this data collection is provided in the table below:

ANNUALIZED ESTIMATES OF HOUR BURDEN

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Drug court team questionnaire	240	3	720	.5	120
Drug court clients focus group questions for guided discussion	600	1	600	1.0	600
Drug court clients—interviews	816	1	816	.5	408
Procedural justice questionnaire	816	1	816	.09	73
Correctional mental health screener—women	408	1	408	.08	33
Correctional mental health screener—men	408	1	408	.08	33
Treatment satisfaction index	816	1	816	.08	65
Total	1,656	.....	2,136	.....	1,128

The estimates in this table reflect the maximum burden for participation in the Adult Treatment Drug Court Cross-Site Evaluation. Burden for drug court personnel is aggregated to reflect total burden over the three-year study period. The drug court personnel questionnaire will be administered three times; once during each of three study years. Burden for the drug court clients is annualized. Focus groups and interviews are one-time events. Some drug court clients will participate in both a focus group and 6-month post-discharge interview.

Written comments and recommendations concerning the proposed information collection should be sent by October 8, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: August 28, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–21511 Filed 9–4–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451] (formerly Docket No. 2004N–0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 022

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: 022'' (Recognition List Number: 022), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic 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: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 022'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*. 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: 022 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993–0002, 301–796–6574.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 of the 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 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**, are identified in table 1 of this document.

TABLE 1.—FEDERAL REGISTER CITATION

February 25, 1998 (63 FR 9561)	May 27, 2005 (70 FR 30756)
October 16, 1998 (63 FR 55617)	November 8, 2005 (70 FR 67713)
July 12, 1999 (64 FR 37546)	March 31, 2006 (71 FR 16313)
November 15, 2000 (65 FR 69022)	June 23, 2006 (71 FR 36121)
May 7, 2001 (66 FR 23032)	November 3, 2006 (71 FR 64718)
January 14, 2002 (67 FR 1774)	May 21, 2007 (72 FR 28500)
October 2, 2002 (67 FR 61893)	September 12, 2007 (72 FR 52142)
April 28, 2003 (68 FR 22391)	December 19, 2007 (72 FR 71924)
March 8, 2004 (69 FR 10712)	September 9, 2008 (73 FR 52358)
June 18, 2004 (69 FR 34176)	March, 18, 2009 (74 FR 11586)
October 4, 2004 (69 FR 59240)	

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 of this document 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: 022

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews 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: 022'' to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others; (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 document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 2.

Old Recognition No.	Replacement Recognition No.	Standard	Change
A. Anesthesia			
1–37	1–80	CGA C–9:2004 (Reaffirmed 2008) Standard Color Marking of Compressed Gas Containers for Medical Use	Withdrawn and replaced with newer version

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
1–68	1–81	CGA V–5:2008 Diameter-Index Safety System Noninterchangeable Low Pressure Connections for Medical Gas Applications	Withdrawn and replaced with newer version
1–51		ASTM F1100–90 (1997) Standard Specification for Ventilators Intended for Use in Critical Care	Withdrawn
1–59		ASTM F1456–01 Standard Specification for Minimum Performance and Safety Requirements for Capnometers	Withdrawn
B. Biocompatibility			
2–64		ANSI/AAMI/ISO 10993–5:1999 Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity	Contact person, Extent of recognition and Relevant guidance
2–82		ASTM F2147–01 Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens	Contact person and Extent of recognition
2–83	2–136	ASTM E1262–88 (Reapproved 2008) Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	Withdrawn and replaced with newer version
2–84	2–137	ASTM E1263–97 (Reapproved 2008) Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes	Withdrawn and replaced with newer version
2–85	2–138	ASTM E1280–97 (Reapproved 2008) Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity	Withdrawn and replaced with newer version
2–87		ISO 10993–10:2002 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-type Hypersensitivity	Extent of recognition and Relevant guidance
2–90	2–139	ASTM E1397–91 (Reapproved 2008) Standard Practice for In Vitro Rat Hepatocyte DNA Repair Assay	Withdrawn and replaced with newer version
2–91	2–140	ASTM E1398–91 (Reapproved 2008) Standard Practice for In Vivo Rat Hepatocyte DNA Repair Assay	Withdrawn and replaced with newer version
2–93		ASTM F763–04 Standard Practice for Short-Term Screening of Implant Materials	Extent of recognition and Contact person
2–94		ASTM F981–04 Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	Extent of recognition and Contact person
2–95	2–141	ASTM F1984–99 (Reapproved 2008) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	Withdrawn and replaced with newer version
2–97	2–142	ASTM F1983–99 (Reapproved 2008) Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications	Withdrawn and replaced with newer version
2–98		ANSI/AAMI/ISO 10993–1:2003 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing	Title, Extent of recognition, Relevant guidance and Contact person
2–99	2–143	ASTM F1904–98 (Reapproved 2008) Standard Practice for Testing the Biological Responses to Particles in vivo	Withdrawn and replaced with newer version
2–100		ASTM E1372–95 (Reapproved 2003) Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	Contact person
2–106	2–144	ASTM F619–03 (Reapproved 2008) Standard Practice for Extraction of Medical Plastics	Withdrawn and replaced with newer version
2–108		ASTM F1905–98(2003) Standard Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity	Contact person and Extent of recognition
2–114		ASTM F1877–05 Standard Practice for Characterization of Particles	Extent of recognition and Contact person

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
2–115		ASTM F895–84 (Reapproved 2006) Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Extent of recognition, Relevant guidance and Contact person
2–116	2–145	ASTM F1439–03 (Reapproved 2008) Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Withdrawn and replaced with newer version
2–118		ANSI/AAMI/ISO 10993–11:2006 Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity	Extent of recognition, Relevant guidance and Contact person
2–119		ASTM F813–07 Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Contact person
2–121	2–146	ASTM F2148–07€1 Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Withdrawn and replaced with newer version
2–122		ASTM F719–81 (Reapproved 2007)€1 Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Contact person and Relevant guidance
2–124		ASTM F750–87 (Reapproved 2007)€1 Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	Extent of recognition, Relevant guidance and Contact person
2–125		ASTM F749–98 (Reapproved 2007)€1 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Extent of recognition, Relevant guidance and Contact person
2–126		ASTM F748–06 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Extent of recognition, Relevant guidance and Contact person
2–128	2–147	USP 32–NF26 Biological Tests <87> 2009 Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version
2–129	2–148	USP 32–NF26 Biological Tests <88> Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version
2–130	2–149	USP 32–NF26 Biological Tests <88> Biological Reactivity Tests, In Vivo Procedure—Preparation of Sample	Withdrawn and replaced with newer version
2–131	2–150	USP 32–NF26 Biological Tests <88> Biological Reactivity Test, In Vivo, Classification of Plastics—Intracutaneous Test	Withdrawn and replaced with newer version
2–132	2–151	USP 32–NF26 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test	Withdrawn and replaced with newer version
2–133		ASTM F1408–97 (Reapproved 2008) Standard Practice for Subcutaneous Screening Test for Implant Materials	Contact person
2–134		ASTM F2065–00 (2006) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Contact person
2–135		AAMI/ANSI/ISO 10993–12:2007 Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials	Extent of recognition, Relevant guidance and Contact person
C. Dental/ENT			
4–69	4–178	ISO 6872:2008 Dentistry—Ceramic Materials	Withdrawn and replaced with newer version
4–73	4–179	ISO 7405: 2008 Dentistry—Evaluation of Biocompatibility of Medical Devices Used in Dentistry	Withdrawn and replaced with newer version
4–175		ANSI ASA S3.46–1997 (R 2007) Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids	Reaffirmation
D. General			

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
5–12	5–47	ISO 10012:2003 Measurement Management Systems—Requirements for Measurement Processes and Measuring Equipment	Withdrawn and replaced with newer version
5–15	5–48	ANSI/ASQ Z1.9–2008 Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming	Withdrawn and replaced with newer version
5–27		IEC 60601–1–1 Ed. 2.0 2000 Medical Electrical Equipment—Part 1–1: General Requirements for Safety—Collateral Standard: Safety requirements for Medical Electrical Systems	Title
5–36		ISO/TR 16142:2006 Medical Devices—Guidance on the Selection of Standards in Support of Recognized Essential Principles of Safety and Performance of Medical Devices	Title
5–41		IEC 60601–1–4 (2000) Consol. Ed. 1.1 Medical Electrical Equipment—Part 1–4: General Requirements for Safety—Collateral Standard: Programmable Electrical Medical Systems	Title
5–44	5–49	IEC 60601–1–8, Ed. 1 Medical Electrical Equipment—Part 1–8: General Requirements for Safety—Collateral Standard: Alarm Systems—Requirements, Tests and Guidelines—General Requirements and Guidelines for Alarm Systems in Medical Equipment	Withdrawn and re-recognized previous version
E. General Hospital/General Plastic Surgery			
6–63	6–216	ISO 8536–7:2009 Infusion Equipment for Medical Use—Part 7: Caps Made of Aluminum-plastics Combinations for Infusion Bottles	Withdrawn and replaced with newer version
6–112		ANSI/AAMI PB70:2003 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities	Contact person
6–118		ASTM F2196–02 Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices	CFR citation and product code
6–144		ASTM D5712—05€1 Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method	Title and Contact person
6–145		ASTM D3578–05€1 Standard Specification for Rubber Examination Gloves	Title and Contact person
6–147		ASTM D6978–05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Contact person and Relevant guidance
6–149		ASTM D7160–05 Standard Practice for Determination of Expiration Dating for Medical Gloves	Contact person
6–150		ASTM D7161–05 Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions	Contact person
6–165		ASTM D6977–04€1 Standard Specification for Polychloroprene Examination Gloves for Medical Application	Title and Contact person
6–167		ASTM D6319–00a (Reapproved 2005)€1 Standard Specification for Nitrile Examination Gloves for Medical Application	Title and Contact person
6–168		ASTM D3577–09€1 Standard Specification for Rubber Surgical Gloves	Withdrawn and replaced with newer version
6–175		ASTM D5151–06 Standard Test Method for Detection of Holes in Medical Gloves	Contact person
6–178		ASTM D6124–06 Standard Test Method for Residual Powder on Medical Gloves	Contact person
6–183		ASTM D5250–06€1 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	Title and Contact person
6–186	6–217	ASTM F1670–08 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	Withdrawn and replaced with newer version

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
6–205	6–218	USP 32:2009 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version
6–206	6–219	USP 32<11>:2009 Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version
6–207	6–220	USP 32:2009 Absorbable Surgical Suture	Withdrawn and replaced with newer version
6–208	6–221	USP 32<881>:2009 Tensile Strength	Withdrawn and replaced with newer version
6–209	6–222	USP 32<861>:2009 Sutures—Diameter	Withdrawn and replaced with newer version
6–210	6–223	USP 32<871>:2009 Sutures Needle Attachment	Withdrawn and replaced with newer version
6–211	6–224	USP 32<11>:2009 Sterile Water for Irrigation	Withdrawn and replaced with newer version
6–212	6–225	USP 32<11>:2009 Heparin Lock Flush Solution	Withdrawn and replaced with newer version
6–213	6–226	USP 32<11>:2009 Sodium Chloride Injection	Withdrawn and replaced with newer version
F. In Vitro Diagnostics			
7–156	7–195	CLSI M02–A10, Performance Standards for Antimicrobial Disk Susceptibility Tests	Withdrawn and replaced with newer version
7–158	7–196	CLSI M07–A8, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically	Withdrawn and replaced with newer version
7–160	7–197	CLSI M35–A2, Abbreviated Identification of Bacteria and Yeast	Withdrawn and replaced with newer version
7–78	7–198	CLSI M23–A3, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters	Withdrawn and replaced with newer version
7–177	7–199	CLSI M100–S19 Performance Standards for Antimicrobial Susceptibility Testing	Withdrawn and replaced with newer version
7–161	7–200	CLSI M48–A, Laboratory Detection and Identification of Mycobacteria	Withdrawn and replaced with newer version
7–102		NCCLS H1–A5, Tubes and Additives for Venous Blood Specimen Collection	Contact Person
7–101		NCCLS H51–A, Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity	Contact Person
7–165		CLSI H20–A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods	Contact Person
7–103	7–201	CLSI H3–A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture	Withdrawn and replaced with newer version
7–81	7–202	CLSI C28–A3 Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory	Withdrawn and replaced with newer version
7–144	7–203	CLSI H04–A6, Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens	Withdrawn and replaced with newer version
G. Materials			
8–32	8–163	ASTM F1586–08 Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10Nickel-3Manganese-2.5Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)	Withdrawn and replaced with newer version

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
8–44	8–164	ASTM F136–08€1 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Withdrawn and replaced with newer version
8–49	8–165	ASTM F1058–08 Standard Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008)	Withdrawn and replaced with newer version
8–50	8–166	ASTM F1091–08 Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R30605)	Withdrawn and replaced with newer version
8–52	8–167	ASTM F1350–08 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	Withdrawn and replaced with newer version
8–53	8–168	ASTM F1472–08€1 Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	Withdrawn and replaced with newer version
8–76	8–169	ASTM F138–08 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer version
8–79	8–170	ASTM F961–08 Standard Specification for 35Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	Withdrawn and replaced with newer version
8–81	8–171	ASTM F1609–08 Standard Specification for Calcium Phosphate Coatings for Implantable Materials	Withdrawn and replaced with newer version
8–86	8–172	ASTM F1926/F1926M–08 Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Granules, Fabricated Forms, and Coatings	Withdrawn and replaced with newer version
8–94	8–173	ASTM F601–03 (Reapproved 2008) Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Withdrawn and replaced with newer version
8–95	8–174	ASTM F629–02 (Reapproved 2007)€1 Standard Practice for Radiography of Cast Metallic Surgical Implants	Withdrawn and replaced with newer version
8–110	8–175	ASTM F1377–08 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Withdrawn and replaced with newer version
8–118	8–176	ASTM F2503–08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Withdrawn and replaced with newer version
8–133	8–177	ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version
8–143	8–178	ASTM F648–07€1 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Withdrawn and replaced with newer version
8–144	8–179	ASTM F754–08 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders	Withdrawn and replaced with newer version
8–146	8–180	ASTM F2066–08 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)	Withdrawn and replaced with newer version
8–148	8–181	ASTM F899–09 Standard Specification for Wrought Stainless Steels for Surgical Instruments	Withdrawn and replaced with newer version
8–152	8–182	ASTM F1537–08 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Withdrawn and replaced with newer version
8–160	8–183	ASTM F560–08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Withdrawn and replaced with newer version

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
8–161	8–184	ASTM F2516–07€2 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials	Withdrawn and replaced with newer version
8–162	8–185	ASTM F451–08 Standard Specification for Acrylic Bone Cement	Withdrawn and replaced with newer version
H. OB-GYN/Gastroenterology			
9–34		ISO 4074:2002/Cor.1:2003(E):, Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 1	Relevant guidance
9–41	9–58	ASTM D6324–08 Standard Test Methods for Male Condoms Made from Polyurethane	Withdrawn and replaced with newer version
9–43		ISO 16038:2005 Rubber condoms—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms	Relevant guidance
9–56		ASTM D3492–08 Standard Specification for Rubber Contraceptives (Male Condoms)	Relevant guidance
9–57		ISO 4074:2002/Cor.2:2008(E) Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 2	Relevant guidance
I. Orthopedics			
11–172	11–211	ASTM F1798–97 (Reapproved 2008) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Withdrawn and replaced with newer version
11–178	11–212	ASTM F1440–92 (Reapproved 2008) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion	Withdrawn and replaced with newer version
11–192	11–213	ASTM F1223–08 Standard Test Method for Determination of Total Knee Replacement Constraint	Withdrawn and replaced with newer version
11–198	11–214	ASTM F0382–99 (Reapproved 2008) Standard Specification and Test Method for Metallic Bone Plates	Withdrawn and replaced with newer version
11–204	11–215	ASTM F897–02 (Reapproved 2007) Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	Withdrawn and replaced with newer version
11–205	11–216	ASTM F1264–03 (Reapproved 2007)€1 Standard Specification and Test Methods for Intramedullary Fixation Devices	Withdrawn and replaced with newer version
11–209	11–217	ASTM F2083–08€1 Standard Specification for Total Knee Prosthesis	Withdrawn and replaced with newer version
J. Radiology			
12–17	12–192	NEMA MS 8–2008 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems	Withdrawn and replaced with new version
12–48	12–193	AIUM AOL 2008 Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment Revision 1- A Standard for How Manufacturers Should Specify Acoustic Output Data	Withdrawn and replaced with newer version
12–58	12–194	ANSI/HPS N43.6–2007 Sealed Radioactive Sources—Classification	Withdrawn and replaced with newer version
12–69	12–195	NEMA MS 6–2008 Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	Withdrawn and replaced with newer version
12–95	12–196	NEMA MS 2–2008 Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images	Withdrawn and replaced with newer version
12–100		NEMA UD 3–2004 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	Contact person

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
12–105		NEMA UD 2–2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3	Contact person
12–139		AIUM AOMS–2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Title and Contact person
12–140		AIUM RTD1–2004 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1	Title and Contact person
12–146		IEC 60601–2–17 (2004) Medical Electrical Equipment—Part 2–17: Particular Requirements for the Safety of Automatically-controlled Brachytherapy Afterloading Equipment	Title
12–147		IEC 60601–2–5: (2000) Medical Electrical Equipment—Part 2–5: Particular Requirements for the Safety of Ultrasonic Physiotherapy Equipment Ed. 2.0	Title
12–169	12–197	IEC 60601–2–22 (1995) Medical Electrical Equipment—Part 2–22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment—Edition 2.0	Withdrawn and re-recognized previous version
12–178		IEC 60601–2–45 Ed. 2.0, (2001), Medical electrical equipment—Part 2–45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices	Title
12–182	12–198	IEC 60601–2–37 (2004), (2005) Amendment 2, Medical Electrical Equipment—Part 2–37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment	Withdrawn and re-recognized previous version
12–185	12–199	IEC 60601–1–3: 1994 Medical Electrical Equipment—Part 1: General Requirements for Safety 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment—First Edition	Withdrawn and re-recognize previous version
12–186	12–200	IEC 60601–2–29 (1999) Medical Electrical Equipment Part 2–29: Particular Requirements for the Safety of Radiotherapy Simulators—Second Edition	Withdrawn and re-recognized previous version
K. Software/Informatics			
13–16	13–29	CLSI LIS01–A2 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems	Withdrawn and replaced with newer version
L. Sterility			
14–55		ANSI/AAMI/ISO 14160:1998/(R) 2008 Sterilization of Single-use Medical Devices Incorporating Materials of Animal Origin—Validation and Routine Control of Sterilization by Liquid Chemical Sterilants	Reaffirmation
14–88		ANSI/AAMI/ ISO 14937:2000 Sterilization of Health Care Products—General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.	Contact person
14–116		ANSI/AAMI ST72:2002 Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Relevant guidance and Extent of recognition
14–135		ANSI/AAMI ST63:2002 Sterilization of Health Care Products—Requirements for the Development, Validation, and Routine Control of an Industrial Sterilization Process for Medical Devices—Dry Heat	Relevant Guidance
14–164		ANSI/AAMI ST81:2004 Sterilization of Medical Devices—Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices	Contact Person
14–195		ANSI/AAMI/ISO 11140–1:2005 Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements	Relevant Guidance, Extent of Recognition and Contact person

TABLE 2.—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
14–220	14–263	ANSI/AAMI ST79:2006/A1:2008 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities	Withdrawn and replaced with newer version
14–223		ANSI/AAMI/ISO 11138–1:2006 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	Relevant Guidance
14–224		ANSI/AAMI/ISO 11137–1:2006 Sterilization of Health Care Products—Radiation—Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Relevant Guidance
14–225		ANSI/AAMI/ISO 11137–2:2006 Sterilization of Health Care Products—Radiation—Part 2: Establishing the Sterilization Dose	Relevant Guidance
14–226		ANSI/AAMI/ISO 11137–3:2006 Sterilization of Health Care Products—Radiation—Part 3: Guidance on Dosimetric Aspects	Relevant Guidance
14–228		ANSI/AAMI/ISO 11135–1:2007 Sterilization of Health Care Products—Ethylene oxide—Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Relevant Guidance
14–261		ANSI/AAMI/ISO 17665–1:2006 Sterilization of Health Care Products—Moist Heat—Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Relevant Guidance
14–119		ANSI/AAMI ST55:2003/(R)2008 Table-top Steam Sterilizers	Reaffirmation
14–71	14–264	ANSI/AAMI ST8:2008 Hospital Steam Sterilizers	Withdrawn and replaced with newer version
14–249	14–265	USP 32:2009 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	Withdrawn and replaced with newer version
14–250	14–266	USP 32:2009 <71> Sterility Tests	Withdrawn and replaced with newer version
14–251	14–267	USP 32:2009 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version
14–252	14–268	USP 32:2009 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version
14–253	14–269	USP 32:2009 <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version
14–254	14–270	USP 32:2009 Biological Indicator for Steam Sterilization—Self Contained	Withdrawn and replaced with newer version
14–246	14–271	USP 32:2009 Biological Indicator for Dry-Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14–247	14–272	USP 32:2009 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14–248	14–273	USP 32:2009 Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14–238		ANSI/AAMI/ISO 11140–5:2007 Sterilization of Health Care Products—Chemical Indicators—Part 5: Class 2 Indicators for Bowie and Dick-type Air Removal Tests	Contact person and Relevant guidance
14–171	14–274	ANSI/AAMI/ISO 15882:2008 Chemical Indicators—Guidance on the Selection, Use, and Interpretation of Results	Withdrawn and replaced with newer version
14–49	14–275	ANSI/AAMI ST41:2008 Ethylene oxide Sterilization in Health Care Facilities: Safety and Effectiveness	Withdrawn and replaced with newer version
14–136		ANSI/AAMI ST67:2003/(R) 2008 Sterilization of Health Care Products—Requirements for Products Labeled ''STERILE''	Reaffirmation and Relevant guidance

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 022.

TABLE 3.

Recognition No.	Title of Standard	Reference No. & Date
A. Biocompatibility		
2–152	Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-type Hypersensitivity Amendment 1	ISO 10993 10:2002/ Amd.1:2006(E)
B. General		
5–46	Sampling Procedures for Inspection by Attributes—Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-lot Inspection	ISO 2859–1:1999/Cor 1:2001
5–50	Medical Devices—Application of Usability Engineering to Medical Devices	IEC 62366:2007
C. In Vitro Diagnostics		
7–204	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts	CLSI M27–A3
D. Materials		
8–186	Standard Guide for Assessment of the Ultra High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices	ASTM F 2759—09
8–187	Implants for Surgery—Hydroxyapatite—Part 1: Ceramic Hydroxyapatite	ISO 13779–1:2008(E)
8–188	Implants for Surgery—Hydroxyapatite—Part 2: Coatings of Hydroxyapatite	ISO 13779–2:2008(E)
E. Neurology		
17–8	Implants for Surgery—Active Implantable Medical Devices Part 3: Implantable Neurostimulators (Neurology)	ISO 14708–3 2008–11–15
F. OB-GYN/Gastroenterology		
9–59	Hemodialysis Systems	ANSI/AAMI RD5:2003/(R) 2008
G. Orthopedics		
11–218	Implants for surgery—Wear of Total Knee-joint Prostheses—Part 3: Loading and Displacement Parameters for Wear-testing Machines with Displacement Control and Corresponding Environmental Conditions for Test	ISO 14243–3:2004 Technical Corrigendum 1
H. Sterility		
14–276	Sterilization of Health Care Products—Moist Heat—Part 2: Guidance on the Application of ISO 17665–1	ISO/TS 17665–2:2009
14–277	Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	USP32:2009 <62>
14–278	Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	ANSI/AAMI/ISO 10993–7:2008
I. Tissue Engineering		
15–14	Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds	ASTM F2603–06
15–15	Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (1H NMR) Spectroscopy	ASTM F2259–03 (Reapproved 2008)

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 minor revisions described in this document into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor 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 the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (See **FOR FURTHER INFORMATION CONTACT**). 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. 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 includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this document announcing ''Modification to the List of Recognized Standards, Recognition List Number: 022'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. 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: 022. These modifications to the list or recognized standards are effective upon publication of this document in the **Federal Register**.

Dated: August 26, 2009.

Catherine M. Cook,

Associate Director for Regulation and Policy.

[FR Doc. E9–21609 Filed 9–4–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Capacity Building Assistance (CBA) To Improve the Delivery and Effectiveness of Human Immunodeficiency Virus (HIV) Prevention Services for High-Risk and/or Racial/Ethnicity Minority Populations, Program Announcement Number PS09–906, Initial Review

DATES: August 28, 2009.

Correction: This notice was published in the **Federal Register** on August 6, 2009, Volume 74, Number 150, page 39333. The date on the original notice has changed.

CONTACT PERSON FOR MORE INFORMATION: Monica Farmer, M.Ed., Public Health Analyst, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, NE., Mailstop E–60, Atlanta, GA 30333. Telephone (404) 498–2277.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 25, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–21510 Filed 9–4–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

2009 Parenteral Drug Association and Food and Drug Administration Joint Regulatory Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) in co-sponsorship with the Parenteral Drug Association (PDA), is announcing a conference entitled ''Securing the Future of Medical Product Quality: A 2020 Vision.'' The workshop helps to achieve objectives set forth in the FDA Modernization Act of 1997, which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public.

Date and Time: The conference will be held on Monday, September 14, 2009 from 8 a.m. to 6 p.m.; Tuesday, September 15, 2009 from 7:15 a.m. to 5:45 p.m.; and Wednesday, September 16 from 7:15 a.m. to 1:15 p.m.

Location: The public workshop will be held at the Renaissance Hotel, 999 9th St., Washington, D.C., 20001; 1–202–898–9000; FAX: 1–202–289–0947.

Contact: *Regarding the conference*: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East-West Hwy., suite 200, Bethesda, MD 20814.

Regarding this document: Ken Nolan, Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, rm. 15–05, Rockville, MD 20857, 301–827–3376.

Registration: You are encouraged to register at your earliest convenience. The PDA registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted in to the conference will receive confirmation. Registration will close after applicable conference is filled. Onsite registration will be available on a space-available basis on the day of the public conference, beginning at 7 a.m. on Monday, September 14, 2009.

The cost of registration is as follows:

PDA Members	$1850.00
PDA Non-members	$2099.00
Government	$700.00
PDA Member Academic/Health Authority.	$700.00