Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 15, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–9737 Filed 5–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 017

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: 017'' (Recognition List Number: 017), 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: 017'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 240–276–3151. 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: 017 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850, 240–276–0533.

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 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 ''Guidance on the 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 Cite
October 16, 1998 (63 FR 55617)
July 12, 1999 (64 FR 37546)
November 15, 2000 (65 FR 69022)
May 7, 2001 (66 FR 23032)
January 14, 2002 (67 FR 1774)
October 2, 2002 (67 FR 61893)
April 28, 2003 (68 FR 22391)
March 8, 2004 (69 FR 10712)

TABLE 1.—Continued

Federal Register Cite
June 18, 2004 (69 FR 34176)
October 4, 2004 (69 FR 59240)
May 27, 2005 (70 FR 30756)
November 8, 2005 (70 FR 67713)
March 31, 2006 (71 FR 16313)
June 23, 2006 (71 FR 36121)
November 3, 2006 (71 FR 64718)

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: 017

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: 017 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 Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
19	ISO 8382:1988: Resuscitators Intended for Use With Humans	Withdrawn	71
48	ASTM F1246–91(2005): Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits	Withdrawn and replaced with newer version	70
B. Biocompatibility			
57	ASTM F895–84(2006): Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Withdrawn and replaced with newer version	115
72	ASTM F1439–03: Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Withdrawn and replaced with newer version	116
86	AAMI/ANSI/ISO 10993–10:2002(E): Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization	Withdrawn—duplicate	87
87	AAMI/ANSI/ISO 10993–10:2002: Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-type Hypersensitivity	Title	
99	ASTM F1904–98(2003): Standard Practice for Testing the Biological Responses to Particles In Vivo	Title	
C. Dental/Ear, Nose, and Throat (ENT)			
60	ANSI/ADA Specification No. 96:2000: Dental Water-Based Cements	Withdrawn and replaced with newer version	143
72	ISO 6877–2006: Dentistry—Root-canal Obturating Points	Withdrawn and replaced with newer version	137
85	ANSI/ADA Specification No. 15:2000, Synthetic Polymer Teeth	Withdrawn and replaced with newer version	138
91	ANSI/ADA Specification No. 80:2001, Dental Materials—Determination of Color Stability	Title	
114	ANSI/ADA Specification No. 48:2004, Visible Light Curing Units	Withdrawn and replaced with newer version	139
D. General			
2	IEC 60601–1, Medical Electrical Equipment—Part 1:General Requirements for Safety	Contact Person	
11	ISO 2859/1995, Sampling Procedures and Tables for Inspection By Attributes	Contact Person	
12	ISO 10012/1993, Quality Assurance Requirements for Measuring Equipment Part 1: Metrological Confirmation System for Measuring Equipment	Contact Person	
14	ANSI Z1.4/1993, Inspection by Attributes	Contact Person	
15	ANSI Z1.9/1993, Inspection by Variables	Contact Person	
18	ASTM D–4332/1991, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Contact Person	
19	ASTM E–876/1995, Standard Practice for Use of Statistics in the Evaluation of Spectrometric Data	Contact Person	
20	ASTM F–1140/1988, Standard Test Method for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications	Contact Person	
27	IEC 60601–1–1:2000, Medical Electrical Equipment—Part 1: General Requirement for Safety; Safety Requirements for Medical Electrical Systems	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
28	IEC 60601–1–2, (Second Edition, 2001), Medical Electrical Equipment—Part 1–2: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests	Extent of Recognition	
29	AAMI/ANSI HE74–2001, Human Factors Design Process for Medical Devices	Contact Person	
31	ISO 15223, Medical Devices—Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied	Contact Person	
32	EN 980:1996+1:1999+A2:2001, Graphical Symbols for use in the Labeling of Medical Devices	Contact Person	
35	AAMI/ANSI/IEC 60601–1–2, Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601–1–-2:2001 is the U.S. version of IEC 60601–1–2:2001, with identical requirements for electromagnetic compatibility (EMC) of medical electrical equipment.)	Standard Organizations	
E. General Hospital/General Plastic Surgery			
114	ISO 11608–1:2000 Pen-injectors for Medical Use—Part 1: Pen-injectors—Requirements and Test Methods	Contact Person	
115	ISO 11608–2:2000 Pen-injectors for Medical Use—Part 2: Needles—Requirements and Test Methods	Contact Person	
116	ISO 11608–3:2000 Pen-injectors for Medical Use—Part 3: Finished Cartridges—Requirements and Test Methods	Contact Person	
66 and 162	ISO 8536–1:2006 Infusion Equipment for Medical Use—Part 1: Infusion Glass Bottles	Withdrawn and replaced with newer version	172
53	ASTM D5151–99 (2006) Standard Test Method for Detection of Holes in Medical Gloves	Withdrawn and replaced with newer version	175
77	ASTM F1862–05 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Withdrawn and replaced with newer version	181
80	ASTM E1112–00 (2006) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature	Withdrawn and replaced with newer version	177
84	ASTM D6124–06 Standard Test Method for Residual Powder on Medical Gloves	Withdrawn and replaced with newer version	178
161	ISO 10555–1:1995/ Amendment 1:1999, Amendment 2:2004 Sterile, Single-use Intravascular Catheters—Part 1: General Requirements	Title	
85	ASTM 5250–06 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	Withdrawn and replaced with newer version	183
E. In Vitro Diagnostics			
91	CLSI EP7–A2, Interference Testing in Clinical Chemistry; Approved Guidelines—Second Edition	Withdrawn and replaced with newer version	127
F. Materials			
1	ASTM F67–06: Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)	Withdrawn and replaced with newer version	129
2	ASTM F75–01: Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	Contact Person	
3	ASTM F90–01: Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
10	ASTM F603–00: Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application	Contact Person	
11	ASTM F620–06: Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants	Withdrawn and replaced with newer version	130
15	ASTM F745–00: Standard Specification for 18 Chromium–12.5 Nickel–2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	Contact Person	
26	ASTM F1314–01: Standard Specification for Wrought Nitrogen Strengthened 22 Chromium—13 Nickel—5 Manganese—2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)	Contact Person	
27	ASTM F1341–99: Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50550, UNS R50700, for Surgical Implant Applications	Withdrawn	
30	ASTM F1537–00: Standard Specification for Wrought Cobalt–28–Chromium–6–Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Contact Person	
32	ASTM F1586–02: Standard Specification for Wrought Nitrogen Strengthened 21 Chromium–10 Nickel–3 Manganese–2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)	Contact Person	
37	ASTM F1813–01: Standard Specification for Wrought Titanium—12 Molybdenum—6 Zirconium—2 Iron Alloy for Surgical Implant (UNS R58120)	Contact Person	
41	ASTM F2066–01: Standard Specification for Wrought Titanium–15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)	Contact Person	
43	ASTM F2146–01: Standard Specification for Wrought Titanium–3Aluminum–2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320)	Contact Person	
44	ASTM F136–02a: Standard Specification for Wrought Titanium–6 Aluminum–4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Contact Person	
45	ASTM F562–02: Standard Specification for Wrought 35Cobalt–35Nickel–20Chromium–10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	Contact Person	
46	ASTM F621–02: Standard Specification for Stainless Steel Forgings for Surgical Implants	Contact Person	
47	ASTM F799–06: Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	Withdrawn and replaced with newer version	131
48	ASTM F899–02: Standard Specification for Stainless Steel for Surgical Instruments	Contact Person	
49	ASTM F1058–02: Standard Specification for Wrought 40Cobalt–20Chromium–16Iron–15Nickel–7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008)	Contact Person	
50	ASTM F1091–02: Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy Surgical Fixation Wire (UNS R30605)	Contact Person	
52	ASTM F1350–02: Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	Contact Person	
53	ASTM F1472–02a: Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
54	ASTM F1580–01: Standard Specification for Titanium and Titanium–6 Aluminum–4 Vanadium Alloy Powders for Coatings of Surgical Implants	Contact Person	
56	ISO 5832–1:1997: Implants for Surgery—Metallic materials—Part 1: Wrought Stainless Steel	Contact Person	
57	ISO 5832–2:1999: Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	Contact Person	
58	ISO 5832–3:1996: Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6–Aluminium 4–Vanadium Alloy	Contact Person	
59	ISO 5832–4:1996: Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum Casting Alloy	Contact Person	
61	ISO 5832–6:1997: Implants for Surgery—Metallic Materials—Part 6: Wrought Cobalt-nickel-chromium-Molybdenum alloy	Contact Person	
62	ISO 5832–9:1992: Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel	Contact Person	
63	ISO 5832–11:1994: Implants for Surgery—Metallic Materials—Part 11: Wrought Titanium 6–aluminium 7 niobium Alloy	Contact Person	
64	ISO 5832–12:1996: Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-chromium-molybdenum Alloy	Contact Person	
66	ISO 6474:1994: Implants for Surgery—Ceramic Materials Based on High Purity Alumina	Contact Person	
68	ISO 13782:1996: Implants for Surgery—Metallic Materials—Unalloyed Tantalum for Surgical Implant Applications	Contact Person	
76	ASTM F138–03: Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Contact Person	
77	ASTM F139–03: Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Contact Person	
79	ASTM F961–03: Standard Specification for Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035]	Contact Person	
80	ASTM F1088–04ae1: Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Withdrawn and replaced with newer version	132
81	ASTM F1609–03: Standard Specification for Calcium Phosphate Coatings for Implantable Materials	Contact Person	
82	ASTM F1713–03: Standard Specification for Wrought Titanium–13 Niobium–13 Zirconium Alloy for Surgical Implant Applications	Contact Person	
85	ASTM F1854–01: Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants	Contact Person	
86	ASTM F1926–03: Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings	Contact Person	
87	ASTM F1978–00e1: Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	Contact Person	
88	ASTM F2024–00: Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	Contact Person	
89	ASTM F1873–98: Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
94	ASTM F601–03: Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Contact Person	
95	ASTM F629–02: Standard Practice for Radiography of Cast Metallic Surgical Implants	Contact Person	
97	ASTM F2129–06: Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version	133
98	ASTM F451–99ae1: Standard Specification for Acrylic Bone Cement	Contact Person	
102	ASTM F2082–06: Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery	Withdrawn and replaced with newer version	134
103	ASTM F1801–97(2004): Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	Contact Person and Type of Standard	
104	ASTM F1108–04: Standard Specification for Titanium–6Aluminum–4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	Contact Person	
106	ASTM F648–04: Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Contact Person	
107	ASTM F746–04: Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	Contact Person	
108	ASTM F1295–05: Standard Specification for Wrought Titanium–6 Aluminum–7 Niobium Alloy for Surgical Implant Applications (UNS R56700)	Contact Person	
110	ASTM F1377–04: Standard Specification for Cobalt–28 Chromium–6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Contact Person	
111	ASTM F1160–05: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Contact Person	
112	ASTM F1044–05: Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Contact Person	
113	ASTM F1147–05: Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Contact Person	
114	ASTM F2255–05: Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading	Contact Person	
115	ASTM F2256–05: Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	Contact Person	
116	ASTM F2258–05: Standard Test Method for Strength Properties of Tissue Adhesives in Tension	Contact Person	
117	ASTM F86–04: Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Contact Person	
119	ASTM F688–05: Standard Specification for Wrought Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)	Contact Person	
120	ASTM F560–05: Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Contact Person	
121	ASTM F2005–05: Standard Terminology for Nickel-Titanium Shape Memory Alloys	Contact Person	
122	ASTM F2063–05: Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
123	ISO 5832–5:2005: Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-chromium-tungsten-nickel Alloy	Contact Person	
125	ASTM F2004–05: Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis	Contact Person	
126	ASTM F561–05a: Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues	Contact Person	
127	ISO 5834–2:1998: Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 2: Moulded Forms	Contact Person	
G. OB-GYN/Gastroenterology			
35	ASTM D6324–05 Standard Test Methods for Male Condoms Made from Synthetic Materials	Withdrawn and replaced with newer version	41
H. Ophthalmic			
3	ISO 9340:1996 Optics and Optical Instruments—Contact lenses—Determination of Strains for Rigid Contact Lenses	Withdrawn	
12	ISO 11980:1997 Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Guidance for Clinical Investigations	Contact Person	
13	ISO 10942:2006 Ophthalmic Instruments—Direct Ophthalmoscopes	Withdrawn and replaced with newer version	37
15	ISO 9394:1998 Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Determination of Biocompatibility By Ocular Study Using Rabbit Eyes	Contact Person	
18	ISO 10943:2006 Ophthalmic Instruments—Indirect Ophthalmoscopes	Withdrawn and replaced with newer version	38
20	ISO 11979–1:2006 Ophthalmic implants—Intraocular Lenses—Part 1: Vocabulary	Withdrawn and replaced with newer version	40
23	ISO 11981:1999 Ophthalmic Optics—Contact Lenses And Contact Lens Care Products—Determination of Physical Compatibility of Contact Lens Care Products With Contact Lenses	Contact Person	
24	ISO 11986:1999 Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Guidelines for Determination of Preservative Uptake and Release	Contact Person	
34	ANSI Z80.20–2004 Ophthalmics—Contact Lenses—Standard Terminology, Tolerances, Measurements and Physicochemical Properties	Contact Person	
I. Orthopedic/Physical Medicine			
73	ISO 5838–1:1995: Implants for Surgery—Skeletal Pins and Wires—Part 1: Material and Mechanical Requirements	Contact Person	
74	ISO 5838–2:1991: Implants for Surgery—Skeletal Pins and Wires—Part 2: Steinmann Skeletal Pins—Dimensions	Contact Person	
75	ISO 5838–3:1993: Implants for Surgery—Skeletal Pins and Wires—Part 3: Kirschner Skeletal Wires	Contact Person	
79	ISO 7206–8:1995: Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components With Application of Torsion	Contact Person	
80	ISO 8828:1988: Implants for Surgery—Guidance on Care and Handling of Orthopaedic Implants	Contact Person	
81	ISO 9583:1993: Implants for Surgery—Non-destructive Testing—Liquid Penetrant Inspection of Metallic Surgical Implants	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
82	ISO 9584:1993: Implants for Surgery—Non-destructive Testing—Radiographic Examination of Cast Metallic Surgical Implants	Contact Person	
83	ISO 13402:1995: Surgical and Dental Hand Instruments—Determination of Resistance Against Autoclaving, Corrosion and Thermal Exposure	Contact Person	
121	ISO 7207–1:1994: Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 1: Classification, Definitions and Designation of Dimensions	Contact Person	
155	ISO 7207–2:1998: Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastics Materials	Contact Person	
163	ASTM F543–02e1, Standard Specification and Test Methods for Metallic Medical Bone Screws	Withdrawn and replaced with newer version	202
166	ASTM F897–02: Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	Contact Person	
167	ASTM F1089–02: Standard Test Method for Corrosion of Surgical Instruments	Contact Person	
168	ASTM F1781–03: Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Contact Person	
171	ASTM F1814–97a(2003): Standard Guide for Evaluating Modular Hip and Knee Joint Components	Contact Person	
172	ASTM F1798–97(2003): Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Contact Person	
175	ASTM F1582–98(2003): Standard Terminology Relating to Spinal Implants	Contact Person	
177	ASTM F1264–03: Standard Specification and Test Methods for Intramedullary Fixation Devices	Contact Person	
178	ASTM F1440–92(2002): Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion	Contact Person	
179	ASTM F2068–03: Standard Specification for Femoral Prostheses—Metallic Implants	Contact Person	
180	ASTM F366–04: Standard Specification for Fixation Pins and Wires	Contact Person	
181	ASTM F1717–04: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Contact Person	
182	ASTM F1800–04: Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Contact Person	
183	ASTM F1875–98(2004): Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface	Contact Person	
185	ASTM F2267–04: Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression	Contact Person	
186	ASTM F2077–03: Test Methods for Intervertebral Body Fusion Devices	Contact Person	
187	ASTM F2193–02: Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	Contact Person	
188	ISO 14243–1:2002: Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 1: Loading and Displacement Parameters for Wear-testing Machines with Load Control and Corresponding Environmental Conditions for Test	Contact Person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
189	ISO 14243–2:2000: Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 2: Methods of Measurement	Contact Person	
190	ISO 14243–3:2004: 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	Contact Person	
191	ISO 14879–1:2000: Implants for Surgery—Total Knee-joint Prostheses—Part 1: Determination of Endurance Properties of Knee Tibial Trays	Contact Person	
192	ASTM F1223–05: Standard Test Method for Determination of Total Knee Replacement Constraint	Contact Person	
J. Radiology			
34	IEC 60601–2–7 (1998) Medical Electrical Equipment—Part 2–7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Generators	Contact Person	
68	NEMA MS 4–2006 Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	Withdrawn and replaced with newer version	151
101	ANSI / IESNA RP–27.1–05 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements	Withdrawn and replaced with newer version	153
104	IEC 60601–2–33 (2006), Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis	Withdrawn and replaced with newer version	161
111	ISO 11554:2006 Optics and Photonics—Lasers and Laser-Related equipment—Test Methods for Laser Beam Power, Energy and Temporal Characteristics	Withdrawn and replaced with newer version	155
K. Software			
1	ISO/IEC 12207:1995 Information Technology—Software Life Cycle Processes	Withdrawn	
3	IEEE/EIA 12207.0–1996 Industry Implementation of International Standard ISO/IEC 12207:1995(ISO/IEC 12207) Standard for Information Technology—Software Life Cycle Processes	Withdrawn	
5	IEEE 1074–1997 Standard for Developing a Software Project Life Cycle Process	Withdrawn	
6	IEEE 1012–2004 Standard for Software Verification and Validation	Withdrawn	
7	AAMI / ANSI SW68:2001 Medical Device Software—Software Life Cycle Processes	Withdrawn	
L. Sterility			
67	ASTM F1140–2005, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications	Withdrawn and replaced with newer version	196
68	ASTM F1585:2000, Standard Guide for Integrity Testing of Porous Barrier Medical Packages	Withdrawn	
69	ASTM F1608:2004, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method	Withdrawn and replaced with newer version	197
89	ASTM F2054–05, Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	Withdrawn and replaced with newer version	198
121	ASTM D4169–05, Standard Practice for Performance Testing of Shipping Containers and Systems	Withdrawn and replaced with newer version	199
122	ASTM F88–2006, Standard Test Method for Seal Strength of Flexible Barrier Materials	Withdrawn and replaced with newer version	200

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
M. Tissue Engineering			
1	ASTM F2064–00(2006): Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application	Withdrawn and replaced with newer version	8

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: 017.

TABLE 3.

Item No.	Title of Standard	Reference No. & Date
A. Anesthesia		
71	Lung Ventilators for Medical use—Particular Requirements for Basic Safety and Essential Performance—Part 5: Gas-powered Emergency Resuscitators	ISO 10651–5:2006
B. Cardiovascular/Neurology		
59	Implants for surgery—Cardiac Pacemakers—Part 3: Low-profile Connectors (IS–1) for Implantable Pacemakers	ISO 5841–3:2000
C. Dental/ENT		
140	Dental Base Metal Casting Alloys—Part 2: Nickel-based Alloys	ISO 6871–2:1994/Amd 1:2005
141	Dental Base Metal Casting Alloys—Part 1: Cobalt-based Alloys	ISO 6871–1:1994
142	Dental Base Metal Casting Alloys—Part 1: Cobalt-based Alloys	ISO 6871–1:1994/Amd 1:2005
D. General		
36	Technical Information Report: Medical Devices—Guidance on the Selection of Standards in Support of Recognized Essential Principles of Safety and Performance of Medical Devices, Second Edition	ANSI/AAMI/ISO TIR 16142:2006
E. General Hospital/General Plastic Surgery		
170	Sterile hypodermic syringes for single use—Part 1: Syringes for Manual Use	ISO 7886–1:1993/ Corrigendum 1:1995
171	Sterile, Single-use Intravascular Catheters- Part 3: Central Venous Catheters	ISO 10555–3:1996/ Corrigendum 1:2002
173	Infusion Equipment for Medical Use—Part 2: Closures for Infusion Bottles	ISO 8536–2:2001/ Corrigendum 1:2003
174	Pen-injectors for Medical Use—Part 4: Requirements and Test Methods for Electronic and Electromechanical Pen-injectors	ISO 11608–4:2006
176	Standard Guide for Assessment of Medical Gloves	ASTM D7103–06
179	Needle-free Injectors for Medical Use—Requirements and Test Methods	ISO 21649:2006
180	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	ASTM F2407–06
182	Medical Electrical Equipment— Part 2–38: Particular Requirements for the Safety of Electrically Operated Hospital Beds	IEC 60601–2–38 1996/Amendment 1:1999
F. In Vitro Diagnostic		
128	Evaluation of Matrix Effects; Approved Guideline—Second Edition	CLSI EP14–A2 2005
129	Quality Control of Microbiological Transport Systems	CLSI M40–A 2003
G. Materials		
135	Standard Test Method for Burst Strength of Surgical Sealants	ASTM F2392–04
136	Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants	ASTM F2458–05

TABLE 3.—Continued

Item No.	Title of Standard	Reference No. & Date
H. OB-GYN/Gastroenterology		
42	Medical electrical equipment—Part 2: Particular Requirements for the Safety of Endoscopic Equipment	IEC 60601–2–18 (1996) Amendment 1 2000
43	Rubber Condoms—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms	ISO 16038:2005
I. Ophthalmic		
43	Ophthalmic Implants—Intraocular lenses—Part 8: Fundamental Requirements	ISO 11979–8:2006
J. Radiology		
150	Information Technology—Digital Compression and Coding of Continuous-tone Still Images—Part 1: Requirements and Guidelines	IEC / ISO 10918–1:1994 Technical Corrigendum 1:2005
152	Medical Electrical Equipment—Part 2–1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV	IEC 60601–2–1 (1998–06), Amendment 1 2002
154	Lasers and Laser-related Equipment—Determination of Laser-induced Damage Threshold of Optical Surfaces—Part 3: Assurance of Laser Power (energy) Handling Capabilities	ISO 11254–3:2006
156	Lasers and Laser-related Equipment—Test Methods for Laser Beam Parameters—Beam Positional Stability	ISO 11670:2003 Technical Corrigendum 1:2004
157	Optics and Optical Instruments—Lasers and Laser-related Equipment—Test Methods for Laser Beam Power (energy) Density Distribution	ISO 13694:2000 Technical Corrigendum 1:2005
158	Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging	NEMA MS 10–2006
159	Determination of Gradient-Induced Electric Fields In Diagnostic Magnetic Resonance Imaging	NEMA MS 11–2006
160	Quantification and Mapping of Geometric Distortion for Special Applications	NEMA MS 12–2006

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 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 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 notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 017'' 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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*.

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: 017. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: May 10, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–9718 Filed 5–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

A Method With Increased Yield for Production of Polysaccharide-Protein Conjugate Vaccines Using Hydrazide Chemistry

Description of Technology: Current methods for synthesis and manufacturing of polysaccharide-protein conjugate vaccines employ conjugation reactions with low efficiency (about twenty percent). This means that up to eighty percent of the added activated polysaccharide (PS) is lost. In addition, inclusion of a chromatographic process for purification of the conjugates from unconjugated PS is required.

The present invention utilizes the characteristic chemical property of hydrazide groups on one reactant to react with aldehyde groups or cyanate esters on the other reactant with an improved conjugate yield of at least sixty percent. With this conjugation efficiency the leftover unconjugated protein and polysaccharide would not need to be removed and thus the purification process of the conjugate product can be limited to diafiltration to remove the by-products of small molecules. The new conjugation reaction can be carried out within one or two days with reactant concentrations between 1 and 25 mg/mL at PS/protein ratios from 1:2 to 3:1, at temperatures between 4 and 40 degrees Centigrade, and in a pH range of 5.5 to 7.4, optimal conditions varying from PS to PS.

Application: Cost effective and efficient manufacturing of conjugate vaccines.

Inventors: Che-Hung Robert Lee and Carl E. Frasch (CBER/FDA).

Patent Status: U.S. Patent Application No. 10/566,899 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E–301–2003/0–US–10); U.S. Patent Application No. 10/566,898 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E–301–2003/1–US–02); International rights available.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-rEPA Conjugate Vaccine

Description of Technology: This invention is a method of immunization against typhoid fever using a conjugate vaccine comprising the capsular polysaccharide of *Salmonella typhi*, Vi, conjugated through an adipic dihydrazide linker to nontoxic recombinant exoprotein A (rEPA) from *Pseudomonas aeruginosa*. The three licensed vaccines against typhoid fever, attenuated *S. typhi* Ty21a, killed whole cell vaccines and Vi polysaccharide, have limited efficacy, in particular for children under 5 years of age, which make an improved vaccine desirable.

It is generally recognized that an effective vaccine against *Salmonella typhi* is one that increases serum anti-Vi IgG eight-fold six weeks after immunization. The conjugate vaccine of the invention increases anti-Vi IgG, 48-fold, 252-fold and 400-fold in adults, in 5–14 years-old and 2–4 years-old children, respectively. Thus this is a highly effective vaccine suitable for children and should find utility in endemic regions and as a traveler's vaccine. The route of administration can also be combined with routine immunization. In 2–5 years old, the protection against typhoid fever is 90% for 4 years. In school age children and in adults the protection could mount to completer protection according to the immunogenicity data.

Application: Immunization against *Salmonella typhi* for long term prevention of typhoid fever in all ages.

Developmental Status: Conjugates have been synthesized and clinical studies have been performed. The synthesis of the conjugates is described by Kossaczka et al. in Infect Immun. 1997 June;65(7):2088–2093. Phase III clinical studies are described by Mai et al. in N Engl J Med. 2003 October 2; 349(14):1390–1391. Dosage studies are described by Canh et al. in Infect Immun. 2004 Nov;72(11):6586–6588.

A safety and immunogenicity study in infants are underway. The aim is to administer the conjugate vaccine with routine infant immunization. Preliminary results show the vaccine is safe in 2 months old infants.

Inventors: Zuzana Kossaczka, Shousun C. Szu, and John B. Robbins (NICHD).

Patent Status: U.S. Patent 6,797,275 issued 28 Sep 2004 (HHS Reference No. E–020–1999/0–US–02); U.S. Patent Application No. 10/866,343 filed 10 Jun 2004 (HHS Reference No. E–020–1999/0–US–03); U.S. Patent Application No. 11/726,304 filed 20 Mar 2007 (HHS Reference No. E–020–1999/0–US–04).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Developmental and Molecular Immunity, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-rEPA Conjugate Vaccine. Please contact John D. Hewes, Ph.D., at 301–435–3121 or *hewesj@mail.nih.gov* for more information.