TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Type of Survey | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Mail questionnaire | 1,000 | 1 | 1,000 | 1 | 1,000 |
| Telephone survey | 2,000 | 1 | 2,000 | .5 | 1,000 |
| Internet or mall intercept survey | 4,000 | 1 | 4,000 | .5 | 2,000 |
| Total | | | | | 4,000 |

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

These estimates assume that as many as one mail survey project, one telephone survey project, and two internet or mall intercept survey projects may be done on an annual basis. Estimates are based on the expected number of respondents necessary to obtain a statistically significant representation of important consumer segments (e.g., users of relevant regulated products, at risk population groups) and the number of labeling options that may need to be tested.

Dated: September 24, 2002..

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–25079 Filed 10–1–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97D–0530]**

### FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 007

**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 will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 007'' (recognition list number: 007), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** The recognition of standards announced in this document will become effective October 2, 2002. Submit written comments concerning this document at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of ''Modifications to the List of Recognized Standards, Recognition List Number: 007'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (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 301–443–8818. Submit written comments concerning this document to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Identify comments with the docket number found in brackets in the heading of this document. You may access this document on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section V of this document for electronic access to the searchable database for the current list of ''FDA Recognized Consensus Standards,'' including recognition list number: 007 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, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 156.

**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 guidance entitled ''Recognition and Use of Consensus Standards.'' This notice described how FDA will implement its standards program recognizing the use of certain standards and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617); July 12, 1999 (64 FR 37546); November 15, 2000 (65 FR 69022); May 7, 2001 (66 FR 23032), and January 14, 2002 (67 FR 1774), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA.

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 this recognition of consensus standards will be effective upon publication in the **Federal Register**. 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.

For each of the recognized standards, FDA provides in the database a supplementary information sheet that includes information such as:

1. Devices affected by the standard;
2. Processes affected by the standard (premarket notification (510(k), premarket approval (PMA), investigational device exemption (IDE), product development protocol (PDP), and quality systems regulation (QSR));
3. Extent of recognition (all or part of the standard, for what purpose the standard is recognized);
4. Related citations in the Code of Federal Regulations that identify the devices covered;
5. Related product codes that are used by FDA to identify the devices covered; and
6. Guidances relevant to the devices affected by the standard.

#### II. Modifications to the List of Recognized Standards, Recognition List Number: 007

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency

will recognize for use in satisfying portions of premarket review submissions for devices. FDA will incorporate these modifications in the list of ''FDA Recognized Consensus Standards'' in the agency's searchable database. FDA is also establishing two new categories of recognized standards: (1) ''Materials'' and (2) ''tissue engineering'' standards. The tables below reflect the changes FDA is making to the list of recognized standards. These changes include:

- Withdrawn and replaced with a newer version
- Withdrawn and transferred to materials
- Contact person
- Transition statement added to the extend of recognition
- Citations and product codes
- Withdrawn
- Title correction
- Product codes and relevant guidance
- Devices affected
- Devices affected and type of standard

The following tables are divided by standards categories, include the two new categories of materials and tissue engineering standards, and identify the old item number, the name of the standard, the specific change, and the new replacement number, if any.

*A. Biocompatibility*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 12 | ASTM F813–01, Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices | Withdrawn and replaced with newer version 56 | |
| 13 | ASTM E895–84 (2001)e1, Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity | Withdrawn and replaced with newer version | 57 |
| 46 | USP 25—NF20, Biological Tests <87>, Biological Reactivity Test, In Vitro—Direct Contact Test | Withdrawn and replaced with newer version | 58 |
| 47 | USP 25—NF20, Biological Tests <88>, Biological Reactivity Test, In Vitro—Elution Test | Withdrawn and replaced with newer version | 59 |
| 48 | USP 25—NF20, Biological Tests <88>, Biological Reactivity Test, In Vivo, Classification of Plastics—Simple Preparation | Withdrawn and replaced with newer version | 60 |
| 49 | USP 25—NF20, Biological Tests <88>, Biological Reactivity Test, In Vivo—Intracutaneous Test | Withdrawn and replaced with newer version | 61 |
| 50 | USP 25—NF20, Biological Tests <88>, Biological Reactivity Test, In Vivo—Systemic Injection Test | Withdrawn and replaced with newer version | 62 |
| 55 | ANSI/AAMI/ISO 10993–6:1995/(R)2001: Biological evaluation of medical devices—Part 6: Test for local effects after implantation | Withdrawn and replaced with newer version | 63 |
| 54 | ANSI/AAMI/ISO 10993–5: Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity | Withdrawn and replaced with change in extent of recognition | 64 |

*B. Cardiovascular/Neurology*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 12 | ASTM F961–96, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035] | Withdrawn and transferred to materials | |
| 21 | ASTM F75–01, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant (UNS R30075) | Withdrawn and transferred to materials | |
| 22 | ASTM F90–01, Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605) | Withdrawn and transferred to materials | |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 24 | ASTM F560–98, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400) | Withdrawn and transferred to materials | |
| 28 | ASTM F1058–97, Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 34 | ASTM F138–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Bar and Wire for Surgical Implants (UNS S31673) | Withdrawn and transferred to materials | |
| 35 | ASTM F562–00, Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 36 | ASTM F136–98e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications | Withdrawn and transferred to materials | |

*C. Dental/ENT*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 01 | ASTM F67–00, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50550, UNS R50700) | Withdrawn and transferred to materials | |
| 02 | ASTM F75–01, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant (UNS R 30075) | Withdrawn and transferred to materials | |
| 03 | ASTM F90–01, Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605) | Withdrawn and transferred to materials | |
| 04 | ASTM F136–98e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 05 | ASTM F138–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Bar and Wire for Surgical Implants (UNS S31673) | Withdrawn and transferred to materials | |
| 06 | ASTM F139–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | Withdrawn and transferred to materials | |
| 07 | ASTM F562–00, Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 08 | ASTM F620–00, Standard Specification for Alpha Beta Titanium Alloy Forgings for Surgical Implants | Withdrawn and transferred to materials | |
| 09 | ASTM F621–97, Standard Specification for Stainless Steel Forgings for Surgical Implants | Withdrawn and transferred to materials | |
| 10 | ASTM F688–00, Standard Specification for Wrought Cobalt-35 Nickel-2.5 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035) | Withdrawn and transferred to materials | |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 11 | ASTM F745–00, Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications | Withdrawn and transferred to materials | |
| 12 | ASTM F799–99, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539) | Withdrawn and transferred to materials | |
| 13 | ASTM F961–96, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035] | Withdrawn and transferred to materials | |
| 14 | ASTM F1088–87 (1992)e1, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation | Withdrawn and transferred to materials | |
| 15 | ASTM F1091–91(2000), Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R 30605) | Withdrawn and transferred to materials | |
| 16 | ASTM F1108–97a, Standard Specification for Ti6A14V Alloy Castings for Surgical Implants (UNS R56406) | Withdrawn and transferred to materials | |
| 17 | ASTM F1185–88(1993)e1, Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants | Withdrawn and transferred to materials | |
| 18 | ASTM F1295–01, Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700) | Withdrawn and transferred to materials | |
| 19 | 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) | Withdrawn and transferred to materials | |
| 20 | ASTM F1341–99, Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50500, UNS R50700, for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 21 | ASTM F1350–01, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5, Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673) | Withdrawn and transferred to materials | |
| 23 | ASTM F1472–00, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy (UNS R56400) for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 24 | ASTM F1537–00, Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | Withdrawn and transferred to materials | |
| 25 | F1580–95e1, Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants | Withdrawn and transferred to materials | |
| 26 | ASTM F1586–02, Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675) | Withdrawn and transferred to materials | |
| 27 | ASTM F1609–95, Standard Specification for Calcium Phosphate Coatings for Implantable materials | Withdrawn and transferred to materials | |
| 28 | ASTM F1713–96, Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 42 | ANSI/ADA Specification No. 3:1994, Dental Impression Compound | Contact person | 42 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 44 | ANSI/ADA Specification No. 11:1968, Agar Impression Material | Contact person | 44 |
| 45 | ANSI/ADA Specification No. 13:1981, Denture Cold-Curing Repair Resin | Contact person | 45 |
| 48 | ANSI/ADA Specification No. 16:1989, Dental Impression Paste Zinc Oxide Eugenol Type | Contact person | 48 |
| 49 | ANSI/ADA Specification No. 17:1983, Denture Base Temporary Relining Resin | Contact person | 49 |
| 50 | ANSI/ADA Specification No. 18:1992, Alginate Impression Materials | Contact person | 50 |
| 51 | ANSI/ADA Specification No. 20:1968, Dental Duplicating Material | Contact person | 51 |
| 52 | ANSI/ADA Specification No. 27:1993, Resin-Based Filling Materials | Contact person | 52 |
| 53 | ANSI/ADA Specification No. 30:1990, Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements | Contact person | 53 |
| 55 | ANSI/ADA Specification No. 48:1983, Ultraviolet Activator and Disclosing Lights | Contact person, update to processes impacted to include quality system regulation | 55 |
| 56 | ANSI/ADA Specification No. 57:1993, Endodontic Sealing Materials | Contact person, update to processes impacted to include quality system regulation | 56 |
| 59 | ANSI/ADA Specification No. 80:2001, Color Stability Test Procedures | Withdrawn and replaced with newer version, update to processes impacted to include quality system regulation | 91 |
| 60 | ANSI/ADA Specification No. 96:1994, Dental-Water-Based Cements | Contact person, update to processes impacted to include quality system regulation | 60 |
| 62 | ISO 1563:1990, Dental Alginate Impression Material | Contact person, update to processes impacted to include quality system regulation | 62 |
| 63 | ISO 1564:1995, Dental Aqueous Impression Materials Based on Agar | Contact person, update to processes impacted to include quality system regulation | 63 |
| 64 | ISO 3107:1998, Dental Zinc Oxide Eugenol Cements and Zinc Oxide Non-Eugenol Cements | Contact person, update to processes impacted to include quality system regulation | 64 |
| 65 | ISO 3336:1993, Dentistry—Synthetic Polymer Teeth | Contact person, update to processes impacted to include quality system regulation | 65 |
| 66 | ISO 4049:1998, Dentistry—Resin-Based Filling Materials | Contact person, update to processes impacted to include quality system regulation | 66 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 69 | ISO 6872:1995, Amendment 1-1997 Dental Ceramic | Contact person, update to processes impacted to include quality system regulation | 69 |
| 71 | ISO 6876:1986, Dental Root Canal Sealing Materials | Contact person, update to processes impacted to include quality system regulation | 71 |
| 72 | ISO 6877:1995, Dental Root Canal Obturating Points | Contact person, update to processes impacted to include quality system regulation | 72 |
| 80 | ISO 9917:1991, Dental Water-Based Cements | Contact person, update to processes impacted to include quality system regulation | 80 |
| 81 | ISO 10139-1:1991, Dentistry—Resilient Lining Materials for Removable Dentures Part 1: Short Term Materials | Contact person, Update to CDRH Offices to include OC/DE2, and update to processes impacted to include quality system regulation | 81 |
| 82 | ISO 10477:1998, Dentistry—Polymer-Based Crown and Bridge Materials | Contact person, update to processes impacted to include quality system regulation | 82 |
| 85 | ANSI/ADA Specification 15:1999, Synthetic Resin Teeth | Contact person, update to processes impacted to include quality system regulation | 85 |
| 86 | ANSI/ADA Specification No. 38:2000, Metal-Ceramic System | Contact person, update to processes impacted to include quality system regulation | 86 |
| 87 | ANSI/ADA Specification No. 69:1999, Dental Ceramic | Contact person, update to processes impacted to include quality system regulation | 87 |
| 88 | ANSI/ADA Specification No. 78:2000, Endodontic Obturating Points | Contact person | 88 |
| 89 | ANSI/ASA Specification No. 53:1999, Polymer-Based Crown and Bridge Resins | Contact Person, update to processes impacted to include quality system regulation | 89 |

*D. General*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 28 | IEC 60601–1–2 (Second Edition, 2001), Medical Electrical Equipment—Part1: General Requirements for Safety; Electomagnetic Compatibility—Requirements and Tests | Transition statement added to the extent of recognition | 28 |

*E. General Hospital/General Plastic Surgery*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 13 | ISO 595/1 First Edition 1986–12–15, Reusable All Glass or Metal-and-Glass Syringes for Medical Use, Part 1: Dimensions | Citations and product codes | 13 |
| 49 | ASTM D6355–98, Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves | Withdrawn | |
| 57 | USP 24 <11>, Sterile Water for Injection | Withdrawn | |
| 62 | ISO 8536–6, First Edition, 1996–04–01, Infusion Equipment for Medical Use—Part 6: Freeze Drying Closures for Infusion Bottles | Citations and product codes | 62 |
| 63 | ISO 8536–7, Second Edition, 1999–09–01, Infusion Equipment, Caps made of Aluminum-Plastic Combinations for Infusion Bottles | Citations and product codes | 63 |
| 76 | ISO 1135–4, Second Edition, 1998–03–15, Transfusion Equipment for Medical Use—Part 4: Transfusion Sets for Single Use | Citations and product codes | 76 |
| 80 | ASTM E1112–00, Standards Specification for Electronic Thermometers for Intermittent Determinations of Patient Temperatures | Contact person | 80 |
| 41 | USP 25, Nonabsorbable Surgical Sutures | Withdrawn and replaced with newer version | 82 |
| 50 | ASTM D6319–00ae3, Standard Specification for Nitrile Examination Gloves for Medical Application | Withdrawn and replaced with newer version | 83 |
| 51 | ASTM D6124–01, Standard Test Method for Residual Powder on Medical Globes | Withdrawn and replaced with newer version | 84 |
| 52 | ASTM D5250–00e4, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application | Withdrawn and replaced with newer version | 85 |
| 54 | ASTM D3578–01ae2, Standard Specification for Rubber Examination Gloves | Withdrawn and replaced with newer version | 86 |
| 55 | ASTM D3577–01ae2, Standard Specification for Rubber Surgical Gloves | Withdrawn and replaced with newer version | 87 |
| 56 | USP 25 <11>, Sterile Sodium Chloride for Irrigation | Withdrawn and replaced with newer version | 88 |
| 58 | USP 25, Absorbable Surgical Sutures | Withdrawn and replaced with newer version | 89 |
| 59 | USP 25 <881>, Tensile Strength | Withdrawn and replaced with newer version | 90 |
| 60 | USP 25 <861>, Sutures—Diameter | Withdrawn and replaced with newer version | 91 |
| 61 | USP 25 <871>, Sutures Needle Attachment | Withdrawn and replaced with newer version | 92 |

*F. Materials*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| Dental 01, Ortho 123 | ASTM F67–00, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50550, UNS R 50700) | Transferred from dental/ENT and orthopaedics | 01 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| Cardio 21, Dental 02, Ortho 86 | ASTM F75–01, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant (UNS R30075) | Transferred from cardiovascular/neurology dental/ENT and orthopaedics | 02 |
| Cardio 22, Dental 03, Ortho 87 | ASTM F90–01, Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605) | Transferred from cardiovascular neurology, dental/ENT and orthopaedics | 03 |
| Cardio 36, Dental 04, Ortho 88 | ASTM F136–98e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications | Transferred from cardiovascular/neurology, dental/ENT and orthopaedics | 04 |
| Cardio 34, Dental 05, Ortho 144 | ASTM F138–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Bar and Wire for Surgical Implants (UNS S31673) | Transferred from cardiovascular/neurology, dental/ENT and orthopaedics | 05 |
| Dental 06, Ortho 125 | ASTM F139–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | Transferred from dental/ENT and orthopaedics | 06 |
| Cardio 24, Ortho 90 | ASTM F560–98, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400) | Transferred from cardiovascular/neurology and orthopaedics | 07 |
| Cardio 35, Dental 07, Ortho 127 | ASTM F562–00, Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications | Transferred from cardiovascular/neurology, dental/ENT and orthopaedics | 08 |
| Ortho 146 | ASTM F603–00, Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application | Transferred from orthopaedics | 10 |
| Dental 08, Ortho 147 | ASTM F620–00, Standard Specification for Alpha Beta Titanium Alloy Forgings for Surgical Implants | Transferred from dental/ENT and orthopaedics | 11 |
| Dental 09, Ortho 97 | ASTM F621–97, Standard Specification for Stainless Steel Forgings for Surgical Implants | Transferred from dental/ENT and orthopaedics | 12 |
| Ortho 148 | ASTM F648–00, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants | Transferred from orthopaedics | 13 |
| Dental 10, Ortho 128 | ASTM F688–00, Standard Specification for Wrought Cobalt-35 Nickel-2.5 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035) | Transferred from dental/ENT and orthopaedics | 14 |
| Dental 11, Ortho 129 | ASTM F745–00, Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications | Transferred from dental/ENT and orthopaedics | 15 |
| Ortho 149 | ASTM F746–87 (1999), Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials | Transferred from orthopaedics | 16 |
| Dental 12, Ortho 130 | ASTM F799–99, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539) | Transferred from dental/ENT and orthopaedics | 17 |
| Ortho 27 | ASTM F899–95, Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments | Transferred from orthopaedics | 18 |
| Cardio 12, Dental 13, Ortho 28 | ASTM F961–96, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035] | Transferred from cardiovascular/neurology, dental/ENT and orthopaedics | 19 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| Cardio 28 | ASTM F1058–97, Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications | Transferred from cardio-vascular/neurology | 20 |
| Dental 14, Ortho 132 | ASTM F1088–87 (1992)e1, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation | Transferred from dental/ ENT and orthopaedics | 21 |
| Dental 15, Ortho 151 | ASTM F1091–91(2000), Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R 30605) | Transferred from dental/ ENT and orthopaedics | 22 |
| Dental 16, Ortho 133 | ASTM F1108–97a, Standard Specification for Ti6A14V Alloy Castings for Surgical Implants (UNS R56406) | Transferred from dental/ ENT and orthopaedics | 23 |
| Dental 17, Ortho 109 | ASTM F1185–88(1993)e1, Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants | Transferred from dental/ ENT and orthopaedics | 24 |
| Dental 18, Ortho 134 | ASTM F1295–01, Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700) | Transferred from dental/ ENT and orthopaedics | 25 |
| Dental 19, Ortho 40 | 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) | Transferred from dental/ ENT and orthopaedics | 26 |
| Dental 20, Ortho 135 | ASTM F1341–99, Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50500, UNS R50700, for Surgical Implant Applications | Transferred for dental/ ENT and orthopaedics | 27 |
| Dental 21, Ortho 154 | ASTM F1350–01, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5, Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673) | Transferred from dental/ ENT and orthopaedics | 28 |
| Dental 23, Ortho 136 | ASTM F1472–00, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy (UNS R56400) for Surgical Implant Applications | Transferred from dental/ ENT and orthopaedics | 29 |
| Dental 24, Ortho 137 | ASTM F1537–00, Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | Transferred from dental/ ENT and orthopaedics | 30 |
| Dental 25, Ortho 139 | ASTM F1580–95e1, Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants | Transferred from dental/ ENT and orthopaedics | 31 |
| Dental 26, Ortho 50 | ASTM F1586–02, Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675) | Transferred from dental/ ENT and orthopaedics | 32 |
| Dental 27, Ortho 51 | ASTM F1609–95, Standard Specification for Calcium Phosphate Coatings for Implantable Materials | Transferred from dental/ ENT and orthopaedics | 33 |
| Ortho 54 | ASTM F1659–95, Standard Test Method for Bending and Shear Testing of Calcium Phosphate Coatings on Solid Metallic Substrates | Transferred from orthopaedics | 34 |
| Dental 28, Ortho 56 | ASTM F1713–96, Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications | Transferred from dental /ENT and orthopaedics | 35 |
| Ortho 116 | ASTM F1801–97, Standard Recommended Practice for Corrosion Fatigue Testing of Metallic Implant Materials | Transferred from orthopaedics | 36 |
| Rad 65 | ASTM F2052–00, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment | Transferred from radiology | 39 |

*G. Obstetrics and Gynecology (OB-GYN)/Gastroenterology*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 08 | ISO 4047–1: 1996(E): Rubber Condoms—Part 1: Requirements | Withdrawn and replaced with newer version | 26 |
| 09 | ISO 4074–2: 1994(E): Rubber Condoms—Part 2: Determination of Length | Withdrawn and replaced with newer version | 26 |
| 10 | ISO 4047–3: 1994(E): Rubber Condoms—Part 3: Determination of Width | Withdrawn and replaced with newer version | 26 |
| 11 | ISO 4047–5: 1996(E): Rubber Condoms—Part 5: Testing for Holes—Water Leak Test | Withdrawn and replaced with newer version | 26 |
| 12 | ISO 4074–6: 1996(E): Rubber Condoms—Part 6: Determination of Bursting Volume and Pressure | Withdrawn and replaced with newer version | 26 |
| 13 | ISO 4074–7: 1996(E): Rubber Condoms—Part 7: Oven Conditioning | Withdrawn and replaced with newer version | 26 |
| 14 | ISO 4047–9: 1996(E): Rubber Condoms—Part 9: Determination of Tensile Properties | Withdrawn and replaced with newer version | 26 |

*H. Orthopaedics*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 27 | ASTM F899–95, Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments | Withdrawn and transferred to materials | |
| 28 | ASTM F961–96, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035] | Withdrawn and Transferred to materials | |
| 40 | 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) | Withdrawn and Transferred to materials | |
| 50 | ASTM F1586–02, Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675) | Withdrawn and Transferred to materials | |
| 51 | ASTM F1609–95, Standard Specification for Calcium Phosphate Coatings for Implantable Materials | Withdrawn and Transferred to materials | |
| 54 | ASTM F1659–95, Standard Test Method for Bending and Shear Testing of Calcium Phosphate Coatings on Solid Metallic Substrates | Withdrawn and Transferred to materials | |
| 56 | ASTM F1713–96, Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications | Withdrawn and Transferred to materials | |
| 86 | ASTM F75–01, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implant (UNS R30075) | Withdrawn and transferred to Materials | |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 87 | ASTM F90–01, Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605) | Withdrawn and Transferred to materials | |
| 88 | ASTM F136–98e1, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications | Withdrawn and transferred to Materials | |
| 90 | ASTM F560–98, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400) | Withdrawn and Transferred to materials | |
| 97 | ASTM F621–97, Standard Specification for Stainless Steel Forgings for Surgical Implants | Withdrawn and Transferred to materials | |
| 109 | ASTM F1185–88(1993)e1, Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants | Withdrawn and transferred to Materials | |
| 116 | ASTM F1801–97, Standard Recommended Practice for Corrosion Fatigue Testing of Metallic Implant Materials | Withdrawn and transferred to materials | |
| 123 | ASTM F67–00, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50550, UNS R 50700) | Withdrawn and transferred to materials | |
| 125 | ASTM F139–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673) | Withdrawn and transferred to materials | |
| 127 | ASTM F562–00, Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 128 | ASTM F688–00, Standard Specification for Wrought Cobalt-35 Nickel-2.5 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035) | Withdrawn and transferred to materials | |
| 129 | ASTM F745–00, Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications | Withdrawn and transferred to materials | |
| 130 | ASTM F799–99, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539) | Withdrawn and transferred to Materials | |
| 132 | ASTM F1088–87 (1992)e1, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation | Withdrawn and transferred to materials | |
| 133 | ASTM F1108–97a, Standard Specification for Ti6A14V Alloy Castings for Surgical Implants (UNS R56406) | Withdrawn and transferred to materials | |
| 134 | ASTM F1295–01, Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700) | Withdrawn and transferred to materials | |
| 135 | ASTM F1341–99, Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50500, UNS R50700, for Surgical Implant Applications | Withdrawn and transferred to materials | |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 136 | ASTM F1472–00, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy (UNS R56400) for Surgical Implant Applications | Withdrawn and transferred to materials | |
| 137 | ASTM F1537–00, Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) | Withdrawn and transferred to materials | |
| 138 | ASTM F1541–01, Standard Specification and Test Methods for External Skeletal Fixation Devices | Withdrawn and replaced with newer version | 158 |
| 139 | F1580–95e1, Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants | Withdrawn and transferred to materials | |
| 144 | ASTM F138–00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Bar and Wire for Surgical Implants (UNS S31673) | Withdrawn and transferred to materials | |
| 146 | ASTM F603–00, Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application | Withdrawn and transferred to materials | |
| 147 | ASTM F620–00, Standard Specification for Alpha Beta Titanium Alloy Forgings for Surgical Implants | Withdrawn and transferred to materials | |
| 148 | ASTM F648–00, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants | Withdrawn and transferred to materials | |
| 149 | ASTM F746–87 (1999), Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials | Withdrawn and transferred to materials | |
| 151 | ASTM F1091–91(2000), Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R 30605) | Withdrawn and transferred to Materials | |
| 154 | ASTM F1350–01, Standard Specification for Wrought 18 Chromium-14 Nickel–2.5, Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673) | Withdrawn and transferred to materials | |

*I. Physical Medicine*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 21 | ISO 7176–6:2001, Wheelchairs—Part 6: Determination of Maximum Speed, Acceleration and Deceleration of Electric Wheelchairs | Withdrawn and replaced with newer version | 29 |
| 22 | ISO 7176–9:2001, Wheelchairs—Part 9: Climatic Tests for Electric Wheelchair | Withdrawn and replaced with newer version | 30 |

*J. Radiology*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 9 | NEMA NU 1–2001, Performance Measurements of Scintillation Cameras | Withdrawn and replaced with newer version | 75 |
| 18 | NEMA NU 2–2001, Performance Measurement of Positron Emission Tomographs | Withdrawn and replaced with newer version | 76 |
| 46 | AIUM RTD1—1998, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1 | Title correction | 46 |
| 61 | UL 122–2001, Standard for Safety of Photographic Equipment—Fourth Edition | Title correction | 61 |
| 62 | UL 187–1998, Standard for Safety X-ray Equipment—Seventh Edition | Title correction | 62 |
| 64 | IEC 60601–2–45, Ed. 2.0, Medical Electrical Equipment: Part 2–45: Particular Requirement for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices | Title correction | 64 |
| 66 | MUS (R 1999), Medical Ultrasound Safety | Title correction | 66 |
| 67 | NEMA MS–1–2001, Determination of Signal to Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images | Withdrawn and replaced with newer version | 77 |
| 70 | NEMA PS 3.15 2000, Digital Imaging and Communication in Medicine (DICOM) Part 15: Security Profile | Withdrawn and replaced with newer version | 78 |
| 73 | UL–122 (R2001), Standard for Safety, Photographic Equipment | Withdrawn | |

*K. Sterility*

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 01 | AOAC 6.2.01:1995, Official Method 955.24, Testing Disinfectants Against Salmonella choleraesuis, Use-Dilution Method | Product codes | 01 |
| 02 | AOAC 6.2.02:1995, Official Method 991.47, Testing Disinfectants Against Salmonella choleraesuis, Hard Surface Carrier Test Method | Product codes | 02 |
| 03 | AOAC 6.2.03:1995, Official Method 991.48, Testing Disinfectants Against Staphylococcus aureus, Hard Surface Carrier Test Method | Product codes | 03 |
| 04 | AOAC 6.2.04:1995, Official Method 955.15, Testing Disinfectants Against Staphylococcus aureus, Use-Dilution Method | Product codes | 04 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 05 | AOAC 6.2.05:1995, Official Method 991.49, Testing Disinfectants Against Pseudomonas aeruginosa, Hard Surface Carrier Test Methods | Product codes and relevant guidance | 05 |
| 06 | AOAC 6.2.06:1995, Official Method 964.02, Testing Disinfectants Against Pseudomonas aeruginosa, Use-Dilution Method | Product codes and relevant guidance | 06 |
| 07 | AOAC 6.3.02:1995, Official Method 955.17, Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes | Product codes and relevant guidance | 07 |
| 08 | AOAC 6.3.05:1995, Official Method 966.04, Sporicidal Activity of Disinfectants | Product codes and relevant guidance | 08 |
| 09 | AOAC 6.3.06:1995, Official Method 965.12, Tuberculocidal Activity of Disinfectants | Product codes and relevant guidance | 09 |
| 10 | ANSI/AAMI ST8: 2001, Hospital Steam Sterilization | Withdrawn and replaced with newer version | 71 |
| 11 | ANSI/AAMI ST19:1994, Biological Indicators for Saturated Steam Sterilization | Withdrawn | |
| 12 | ANSI/AAMI ST21:1994, Biological Indicators for Ethylene Oxide Sterilization Processes in Health Care Facilities | Withdrawn | |
| 14 | AAMI/ANSI ST33:1992, Guidance for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities | Devices affected | 72 |
| 19 | AAMI/ANSI ST46:1992, Good Hospital Practice Steam Sterilization and Sterility Assurance | Devices affected, correction to type of standard, and relevant guidance | 73 |
| 22 | ANSI/AAMI ST60:1996, Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements | Extent of Recognition and relevant guidance | 74 |
| 25 | AAMI/ANSI/ISO 11135:1994, Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization | Relevant guidance | 25 |
| 26 | AAMI/ANSI/ISO 11137:1994, Sterilization of Health Care Products—Requirements for Validation and Routine Control-Radiation Sterilization and ISO 11137:1995 (AMENDMENT 1:2001) | Withdrawn and replaced with newer version, relevant guidance | 75 |
| 37 | AAMI/ANSI/ISO 10993–7:1995(R) 2001, Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals | Withdrawn and replaced with newer version, relevant guidance | 76 |
| 38 | ANSI/AAMI ST24:1999, Automatic General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities | Devices affected and type of standard | 77 |
| 39 | USP 25:2002, Biological Indicator for Dry-Heat Sterilization Paper Carrier | Withdrawn and replaced with newer version | 78 |
| 40 | USP 25:2002, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier | Withdrawn and replaced with newer version | 79 |
| 41 | USP 25:2002, Biological Indicator for Steam Sterilization, Paper Carrier | Withdrawn and replaced with newer version | 80 |
| 42 | USP 25:2002, <61> Microbial Limits Test | Withdrawn and replaced with newer version | 81 |

| Old Item No. | Standard | Change | Replacement Item No. |
|---|---|---|---|
| 43 | USP 25:2002, Sterility Test <71> | Withdrawn and replaced with newer version | 82 |
| 44 | USP 25:2002, <85>, Biological Tests and Assays, Bacterial Endotoxin Test (LAL) | Withdrawn and replaced with newer version | 83 |
| 45 | USP:2002 <151> Pyrogen Test (USP Rabbit Test) | Withdrawn and replaced with newer version | 84 |
| 46 | USP:2002 <1211> Sterilization and Sterility Assurance of Compendial Articles | Withdrawn and replaced with newer version | 85 |
| 49 | AAMI/ANSI ST41:1999, Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness | Citations, product codes and relevant guidance | 49 |
| 52 | ANSI/AAMI ST59:1999, Sterilization of Health Care Products—Biological Indicators Part 1: General Requirements | Relevant guidance | 52 |
| 53 | AAMI/ANSI ST 66:1999, Sterilization of Health Care Products—Chemical Indicators—Part 2: Class 2 Indicators for Air Removal Test Sheets and Packs | Relevant guidance | 53 |
| 65 | ASTM F1980:2002, Standard Guide for Accelerated Aging of Sterile Medical Device Packages | Withdrawn and replaced with newer version | 86 |
| 66 | USP 25:2002, <161> Transfusion and Infusion Assemblies and Similar Medical Devices | Withdrawn and replaced with newer version | 87 |

## III. Listing of New Entries

FDA is adding new entries to the list of recognized standards as follows:

### *A. Biocompatibility*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 65 | Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials | ASTM F2065–00 |
| 66 | Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA) | ASTM F2148–01 |
| 67 | Standard Practice for Assessment of Hemolytic Properties of Materials | ASTM F756–00 |

### *B. Cardiovascular/Neurology*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 45 | Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms | ANSI/AAMI EC57–98 |
| 46 | Standard Test Method for Measuring Recoil of Balloon-Expandable Stents | ASTM F2079–00 |
| 47 | Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents | ASTM F2081–02 |
| 48 | Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices | ASTM F2129–01 |

### *C. Dental/Ear, Nose, and Throat (ENT)*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 92 | Dental Brazing Alloys | ANSI/ADA Specification No. 88:2000 |
| 93 | Methods of Measurement of Compatibility Between Wireless Communication Devices and Hearing Aids | ANSI C63.19:2001 |

*D. General Hospital/General Plastic Surgery*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 93 | Sterlie Water for Irrigation | USP 25 |
| 94 | Heparin Lock Flush Solution | USP 25 |
| 95 | Sodium Chloride Injection | USP 25 |
| 96 | Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus | ASTM F2101–01 |

*E. In Vitro Devices*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 62 | Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard | NCCLS: AUTO04–A |
| 63 | Laboratory Automation: Electromechanical Interfaces; Approved Standard | NCCLS: AUTO05–A |
| 64 | Point-of-Care Connectivity; Approved Standard | NCCLS: POCT1–A |

*F. Materials*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 09 | Standard Specification for Wrought Cobalt-20 Nickel-20 Chromium-3.5 Molybdenum-3.5 Tungsten-5 Iron Alloy for Surgical Implant Applications (UNS R30563) | ASTM F563–00 |
| 37 | Standard Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant (UNS R58120) | ASTM F1813–01 |
| 38 | Standard Terminology for Nickel-Titanium Shape Memory Alloys | ASTM F2005–00 |
| 40 | Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants | ASTM F2063–00 |
| 41 | Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150) | ASTM F2066–01 |
| 42 | Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants | ASTM F2119–01 |
| 43 | Standard Specification for Wrought Titanium-3 Aluminum-2.5 Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320) | ASTM F2146–01 |

*G. OB-GYN/Gastroenterology*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 26 | Natural Latex Rubber Condoms—Requirements and Test methods | ISO 4074:2000(E) |
| 27 | Standard Test Methods for Male Condoms Made from Synthetic Materials | ASTM D6324–99a |

*H. Ophthalmic*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 30 | Intraocular Lenses | ANSI Z80.7:2001 |

*I. Radiology*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 79 | High Voltage X-ray Cables and Receptacles | NEMA XR 7–1995 (R2000) |
| 80 | Power Supply Guidelines for X-ray Machines | NEMA XR 9–1984 (R1994, R2000) |
| 81 | Mechanical Safety Standard for Power Driven Motions of Electromedical Equipment | NEMA XR 13–1990 (R1995, R2000) |
| 82 | Recommended Practices for Load Bearing Mechanical Assemblies Used in Diagnostic Imaging | NEMA XR 14–1990 (R1995, R2000) |
| 83 | Medical Electrical Equipment, Part 2–37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment | IEC 60601–2–37 (2001–07) |
| 84 | Consol. Ed. 1.2 (incl. am1+am2), Safety of Laser Products—Part 1: Equipment Classification, Requirements and User's Guide | IEC 60825–1 (2001–08) |
| 85 | Ed. 2.0, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment | IEC 60601–2–22 (1995–11) |

*J. Sterility*

| Item No. | Title of Standard | Reference No. and Date |
|---|---|---|
| 88 | 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 | ANSI/AAMI/ISO 14937:2000 |
| 89 | Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates | ASTM F2054–00 |
| 90 | Standard Test Methods for Pressure Decay Leak Test for Nonporous Flexible Packages With and Without Restraining Plates | ASTM F2095–01 |
| 91 | Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test) | ASTM F2096–1 |
| 92 | Standard Guide for Design and Evaluation of Primary Packaging for Medical Products | ASTM F2097–01 |
| 93 | Biological Indicator for Steam Sterilization—Self Contained | USP 25:2002 |

### IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under 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.

### V. Electronic Access

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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 this 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: 007'' 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 data base for ''FDA Recognized Consensus Standards,'' through hyperlinks at *http://www.fda.gov/cdrh/stdsprog.html*. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, at *http://www.fda.gov/cdrh/fedregin.html*.

### VI. Submission of Comments

You may, at any time, submit to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**) written comments regarding this document. You should submit two copies of any comments, except that individuals may submit one copy. You must identify comments 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: 007.''

Dated: September 18, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–24954 Filed 10–1–02; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02D–0389]**

### Draft Guidance for Industry on Nonclinical Studies for Development of Pharmaceutical Excipients; 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 entitled ''Nonclinical Studies for Development of Pharmaceutical Excipients.'' The draft guidance document provides guidance concerning development of safety profiles to support use of new excipients as components of drug or biological products. It is intended for use by reviewers within both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and by interested individuals in industry. The goals of this document are to foster and expedite the development of new excipients, communicate to industry current CDER and CBER thoughts pertaining to safety data needed to support excipient development, and increase uniformity within CDER and CBER on expectations for the nonclinical development of excipients.

**DATES:** Submit written or electronic comments on the draft guidance by December 31, 2002. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER-FAX or 301–827–3844. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5482, or Martin D. Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5349.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Studies for Development of Pharmaceutical Excipients.'' Excipients are potential toxicants. It is important to perform risk-benefit assessments on excipients for use in drug products and to establish permissible limits for these compounds. These activities necessitate the availability of safety data. Consequently, there is a perception that development of new excipients is resource intensive. With proper planning, however, it is often possible to assess the toxicology of an excipient in a relatively efficient manner. Moreover, CDER and CBER recognize that existing human data for some excipients may substitute for nonclinical safety data, and use in previously approved products or GRAS status as a food additive will continue to receive consideration. This draft