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.

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BILLING CODE 4160–01–S

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