October 27, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–10298 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Dental Products Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 22, 2003, from 9:30 a.m. to 4:30 p.m.

Location: Gaithersburg Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, via e-mail at *mea@cdrh.fda.gov,* or by phone: 301–827–5283, ext. 123. Please call the FDA Advisory Committee Information Line at 800–741–8138 (301–443–0572 in the Washington, DC area), code 12518, for updated information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a petition to reclassify tricalcium phosphate granules for dental bone repair (21 CFR 872.3930) from class III to class II (special controls). Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.* Material will be posted on May 21, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 7, 2003. Oral presentations from the public will be scheduled for approximately 60 minutes at the beginning of committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 7, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed committee deliberations: On May 22, 2003, from 4 p.m. to 4:30 p.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: April 21, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–10299 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0077]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 008

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 008'' (Recognition List Number: 008) will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of ''Modification to the List of Recognized Standards, Recognition List Number: 008'' 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 or to recommend additional standards for recognition to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section VI of this document for electronic access to the searchable database for the current list of ''FDA Recognized Consensus Standards,'' including Recognition List Number: 008 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 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 standard recognition program 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), January 14, 2002 (67 FR 1774), and October 2, 2002 (67 FR 61893), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA.

The agency maintains ''html'' and ''pdf'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information.

II. Modifications to the List of Recognized Standards, Recognition List Number: 008

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of ''FDA Recognized Consensus Standards'' in the agency's searchable database. FDA will use the term ''Recognition List Number: 008'' to identify: (1) Supplementary information sheets for standards added to the list for the first time, (2) standards added to replace withdrawn standards, (3) recognized standards for which minor revisions are made to clarify the application of the standards, and (4) standards withdrawn with no replacement.

In the following charts, FDA describes: (1) Modifications that involve the withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the addition of certain recognized standards with revisions to the supplementary information sheets involving changes in significant applications of the standards.

In section III, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

A. Anesthesia

Old Item No.	Standard	Change	Replacement Item No.
12	ISO 5361:1999 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Withdrawn and replaced with newer version.	35
13	ISO 5361–2:1993 Tracheal Tubes—Part 2: Oro-tracheal and Naso-tracheal tubes of Magill Type (plain and cuffed).	Withdrawn and integrated into another standard.	(35)
14	ISO 5361–3:1984 Tracheal Tubes—Part 3: Murphy Type.	Withdrawn and integrated into another standard.	(35)
16	ISO 5361–5:1984 Tracheal Tubes—Part 5: Requirements and Methods of Test for Cuffs and Tubes.	Withdrawn and integrated into another standard.	(35)
17	ISO 5366–3:2001 Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 3: Paediatric tracheostomy tubes.	Withdrawn and replaced with newer version.	36
26	CGA C–9:1988 Edition: 3 Title: Standard Color Marking of Compressed Gas Containers Intended for Medical Use.	Withdrawn and replaced with newer version.	37
27	CGA V–1:2001 Edition: 9 Title: Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections.	Withdrawn and replaced with newer version.	38
28	CGA V–5:2000 Edition: 4 Title: Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications).	Withdrawn and replaced with newer version.	39
29	CGA V–7.1: 1997 Edition: 1 Title: Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases.	Withdrawn and replaced with newer version.	40
22	NFPA 99 Standard for Health Care Facilities CHAPTER 19—Hyperbaric Facilities.	Withdrawn and replaced with newer version.	41

B. Biocompatibility

Old Item No.	Standard	Change	Replacement Item No.
7	ASTM F719–81(2002)e1, Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation.	Withdrawn and replaced with newer version.	68
30	ASTM F720–81(2002)e1, Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test.	Withdrawn and replaced with newer version.	69
32	ASTM F750–87(2002)e1, Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse.	Withdrawn and replaced with newer version.	70

C. Cardiovascular/Neurology

Old Item No.	Standard	Change	Replacement Item No.
46	ASTM F2079–02 Standard Test Methods for Measuring Recoil of Balloon-Expandable Stents.	Recognize newer year date version.	49

D. Dental/ENT

Old Item No.	Standard	Change	Replacement Item No.
48	ANSI/ADA Specification No. 16:1989, Dental Impression Paste Zinc Oxide—Eugenol Type.	Correction in title (dash between oxide and eugenol).	
64	ISO 3107:1988, Dental Zinc Oxide/Eugenol Cements and Zinc Oxide Non-Eugenol Cements.	Correction in title (slash between oxide and eugenol).	
66	ISO 4049:1988, Dentistry-Resin—Based Filling Materials.	Correction in year date (1988 instead of 1998).	
86	ANSI/ADA Specification No. 38:2000, Metal-Ceramic Systems.	Correction in title (change to systems).	

E. General

Old Item No.	Standard	Change	Replacement Item No.
6	IEC 60601–1–2, (First Edition, 1993–04), Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests.	Re-recognize	6
28	IEC 60601–1–2, (Second Edition), Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests.	Extension of time period for the transition statement.	28

H. General Hospital/ General Plastic Surgery

Old Item No.	Standard	Change	Replacement Item No.
81	ASTM E1061	Title correction	81

I. In Vitro Devices

Old Item No.	Standard	Change	Replacement Item No.
30	NCCLS H15–A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition.	Revision	71
45	NCCLS M11–A5, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Fifth Edition.	Revision	75
10	NCCLS M23–A2, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline—Second Edition.	Revision	78
1	NCCLS C28–A2, How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition.	Revision	81
20	NCCLS C34–A2, Sweat Testing: Collection and Quantitative Analysis; Approved Guideline—Second Edition.	Revision	82
5	NCCLS H18–A2, Procedures for the Handling and Processing of Blood Specimens; Approved Guideline.	Withdraw	57
8	NCCLS M2–A7, Performance Standards for Antimicrobial Disk Susceptibility Tests—Sixth Edition; Approved Standard.	Withdraw	55
28	NCCLS H11–A3, Procedure for the Collection of Arterial Blood Specimens; Approved Standard.	Withdraw	58
44	NCCLS M7–A5, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria Tests for Bacteria That Grow Aerobically—Fourth Edition; Approved Standard.	Withdraw	56

J. Materials

Old Item No.	Standard	Change	Replacement Item No.
1	ASTM F67–00, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).	Clarification to extent of recognition with regard to biocompatibility requirements.	
2	ASTM F75–01, Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
3	ASTM F90–01, Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy for Surgical Implant Applications (UNS R30605).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
4	ASTM F136–02, Standard Specification for Wrought Titanium–6 Aluminum–4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).	Withdrawn and replaced with newer version. Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	44

Old Item No.	Standard	Change	Replacement Item No.
5	ASTM F138–00, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
6	ASTM F139–00, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673).	Clarification to extent of recognition with regard to biocompatibility requirements.	
7	ASTM F560–98, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
8	ASTM F562–02, Standard Specification for Wrought 35 Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy for Surgical Implant Applications (UNS R30035).	Withdrawn and replaced with newer version. Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	45
9	ASTM F563–00, Standard Specification for Wrought Cobalt–20 Nickel–20 Chromium–3.5 Molybdenum–3.5 Tungsten–5 Iron Alloy for Surgical Implant Applications (UNS R30563).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
10	ASTM F603–00, Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application.	Clarification to extent of recognition with regard to biocompatibility requirements.	
11	ASTM F620–00, Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants.	Clarification to extent of recognition with regard to biocompatibility requirements.	
12	ASTM F621–02, Standard Specification for Stainless Steel Forgings for Surgical Implants.	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	46
13	ASTM F648–00, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.	Clarification to extent of recognition with regard to biocompatibility requirements.	
14	ASTM F688–00, Standard Specification for Wrought Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Clarification to extent of recognition with regard to biocompatibility requirements.	
15	ASTM F745–00, Standard Specification for 18 Chromium–12.5 Nickel–2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications.	Clarification to extent of recognition with regard to biocompatibility requirements.	
17	ASTM F799–02, Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539).	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	47
18	ASTM F899–02, Standard Specification for Stainless Steel for Surgical Instruments.	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	48

Old Item No.	Standard	Change	Replacement Item No.
19	ASTM F961–96, Standard Specification for Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035).	Cardiovascular contact person. Clarification to extent of recognition with regard to biocompatibility requirements.	
20	ASTM F1058–02, Standard Specification for Wrought 40 Cobalt–20 Chromium–16 Iron–15 Nickel–7 Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008).	Withdrawn and replaced with newer version. Cardiovascular contact person change. Clarification to extent of recognition with regard to biocompatibility requirements.	49
21	ASTM F1088–87(1992)e1, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Clarification to extent of recognition with regard to biocompatibility requirements.	
22	ASTM F1091–02, Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy Surgical Fixation Wire (UNS R30605).	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	50
23	ASTM F1108–02, Standard Specification for Titanium–6 Aluminum–4 Vanadium Alloy Castings for Surgical Implants (UNS R56406).	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	51
24	ASTM F1185–88 (1993)e1, Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants.	Discontinued by ASTM in 2002, no replacement.	Withdrawn
25	ASTM F1295–01, Standard Specification for Wrought Titanium–6 Aluminum–7 Niobium Alloy for Surgical Implant Applications (UNS R56700).	Clarification to extent of recognition with regard to biocompatibility requirements.	
26	ASTM F1314–01, Standard Specification for Wrought Nitrogen Strengthened 22 Chromium-13 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910).	Clarification to extent of recognition with regard to biocompatibility requirements.	
27	ASTM F1341–99, Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50550, UNS R50700, for Surgical Implant Applications.	Clarification to Extent of Recognition with regard to biocompatibility requirements.	
28	ASTM F1350–02, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	52
29	ASTM F1472–02, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	53
30	ASTM F1537–00, Standard Specification for Wrought Cobalt–28–Chromium–6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).	Clarification to extent of recognition with regard to biocompatibility requirements.	
31	ASTM F1580–01, Standard Specification for Titanium and Titanium–6 Aluminum–4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Withdrawn and replaced with newer version. Clarification to extent of recognition with regard to biocompatibility requirements.	54

Old Item No.	Standard	Change	Replacement Item No.
32	ASTM F1586–02, Standard Specification for Wrought Nitrogen Strengthened 21 Chromium–10 Nickel–3 Manganese–2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675).	Clarification to extent of recognition with regard to biocompatibility requirements.	
33	ASTM F1609–95, Standard Specification for Calcium Phosphate Coatings for Implantable Materials.	Clarification to extent of recognition with regard to biocompatibility requirements.	

K. Orthopedic

Old Item No.	Standard	Change	Replacement Item No.
57	ASTM F1717–01 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.	159
98	ASTM F629–02 Standard Practice for Radiography of Cast Metallic Surgical Implants.	Withdrawn and replaced with newer version.	160
153	ASTM F1264–01 Standard Specification and Test Methods for Intramedullary Fixation Devices.	Withdrawn and replaced with newer version.	161
156	ASTM F564–02 Standard Specification and Test Methods for Metallic Bone Staples.	Withdrawn and replaced with newer version.	162
157	ASTM F543–02 Standard Specification and Test Methods for Metallic Medical Bone Screws.	Withdrawn and replaced with newer version.	163
158	ASTM F1541–02 Standard Specification and Test Methods for External Skeletal Fixation Devices.	Withdrawn and replaced with newer version.	164

L. Sterility

Old Item No.	Standard	Change	Replacement Item No.
71	ANSI/AAMI ST8:2001, Hospital Steam Sterilizers	Change in Title (Sterilizers instead of Sterilization).	
77	ANSI/AAMI ST24:1999, Automatic General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities, 3rd. Edition.	Change in title (add third edition)	
91	ASTM F2096–02, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test).	Recognize newer year version (Should be 02 instead of 01).	

IV. Listing of New Entries

The listing of new entries and consensus standards added as ''Modifications to the List of Recognized Standards,'' under Recognition List Number: 008, is as follows:

A. Anesthesia

Item No.	Title of Standard	Reference No. and Date
42	Anaesthetic vaporizers—Agent-specific filling systems	ISO 5360:1993
43	Anaesthetic reservoir bags	ISO 5362:2000

Item No.	Title of Standard	Reference No. and Date
44	Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 1: Tubes and connectors for use in adults.	ISO 5366–1:2000

B. General

Item No.	Title of Standard	Reference No. and Date
30	Medical Electrical Equipment—Part 1–2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility—Requirements and Tests.	ANSI/AAMI/IEC 60601–1–2:2001

C. In Vitro Devices

Item No.	Title of Standard	Reference No. and Date
65	Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.	NCCLS EP5–A:1999
66	Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline.	NCCLS EP10–A:1998
67	Evaluation of Matrix Effects; Approved Guideline	NCCLS EP14–A:2001
68	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition.	NCCLS GP19–A2:2001
69	Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fourth Edition.	NCCLS H3–A4:1998
70	Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition.	NCCLS H4–A4:1999
72	Clinical Application of Flow Cytometry: Quality Assurance Immunophenotyping of Lymphocytes; Approved Guideline.	NCCLS H42–A:1998
73	Clinical Evaluation of Immunoassays; Approved Guideline	NCCLS I/LA21–A:2002
74	Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard.	NCCLS M6–A:1996
76	Laboratory Diagnosis of Blood-Borne Parasitic Diseases; Approved Guideline.	NCCLS M15–A:2000
77	Quality Assurance for Commerically Prepared Microbiological Culture Media—Second Edition; Approved Standard.	NCCLS M22–A2:1996
79	Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline.	NCCLS M28–A:1997
80	Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline.	NCCLS MM1–A:2000
83	Blood Gas and pH Analysis and Related Measurements; Approved Guideline.	NCCLS C46–A:2001
84	Stability Testing of In Vitro Diagnostic Reagents	EN 13640:2001

C. Materials

Item No.	Title of Standard	Reference No. and Date
30	Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests.	ANSI/AAMI/IEC 60601–1–2:2001
31	Symbols to be used with medical device labels, labeling and information to be supplied.	ISO 15223:2000
32	Graphical symbols for use in the labeling of medical devices.	EN 980:1996+A1:1999+A2:2001
55	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.	ASTM F2182–02

D. Tissue Engineering

Item No.	Title of Standard	Reference No. and Date
1	Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Products Application.	ASTM F2064:2000
2	Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications.	ASTM F2103:2001

IV. List of Recognized Standards

FDA maintains the agency's current list of ''FDA Recognized Consensus Standards'' in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

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: 008'' 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*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. 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: 008.'' These modifications to the list of recognized standards are effective upon publication of this notice.

Dated: April 7, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–10417 Filed 4–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0117]

Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the criteria it will use to accredit persons for the purpose of conducting inspections of eligible device manufacturers under section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which established an ''inspection by accredited persons'' program. The new law requires FDA to publish in the **Federal Register** the criteria it will use to accredit persons to conduct inspections of eligible device establishments. These criteria are set out in this document and will become effective immediately after approval by the Office of Management and Budget (OMB) of the collection of information proposed by FDA in connection with this program. At that time, FDA will begin accepting applications for this program. In this document, FDA is also announcing the availability of a guidance document that will provide information for those interested in participating in this newly-created program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff and Third Parties.'' In accordance with the agency's good guidance practices (GGPs), the guidance remains subject to comment at any time. FDA is taking these actions to implement provisions of MDUFMA.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section VI for information on electronic access to the guidance. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: http://www.fda.gov/dockets/ecomments. Identify comments with the docket number found in brackets within the heading of this document.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Director, Division of Small Manufacturers, International and Consumers Assistance, Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–6597 ext. 124.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to perform inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. The new law requires FDA within 180 days from the date MDUFMA was signed into law to ''publish in the **Federal Register** criteria to accredit or deny accreditation to persons who request to perform'' these inspections (section 704(g)(2) of the act). Under section 704(g)(2) of the act, through publication of this **Federal Register** document, the criteria set out in section II of this document will be binding on those persons who apply to become APs under this program. The criteria will be in effect immediately following approval by the OMB of the collection of information proposed by FDA in connection with this program. At that time, FDA will begin accepting applications for accreditation.

FDA is also issuing a guidance document that repeats the criteria it will use for accrediting APs. The guidance also addresses other aspects of this program such as the appropriate format and content for accreditation applications. The guidance is discussed further in section III of this document. Although it was not feasible to obtain comments before issuing the guidance due to tight statutory deadlines, in accordance with this agency's GGP procedures, FDA will accept comments on the guidance at any time.

The new law requires that no more than 15 firms receive accreditation during the 12 months following publication of this **Federal Register** document. In addition, on or before October 26, 2003, FDA must make available on its Web site a list of accredited firms that may conduct inspections and the specific information about the scope of their accreditation. Therefore, in order to comply with this statutory timeframe, FDA will not accept any applications for 2003 after August 25, 2003. The list of APs will be updated periodically but no later than 30 days after a new person is accredited. This update will show any withdrawal of accreditation or any change in activities for which an AP is accredited.

II. Accreditation Criteria

This section describes the criteria FDA will apply when making decisions about whether to accredit persons who request to conduct inspections of eligible class II and class III device manufacturers in lieu of FDA inspection. The guidance document entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties,'' repeats these criteria and provides suggestions on how applicants can address them in their application.

A. Minimum Requirements

Section 704(g)(3) of the act describes the minimum requirements that an AP must meet in order to be accredited by FDA. These requirements are that an AP:

1. May not be a Federal Government employee;

2. Shall be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of