requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 21 CFR 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18559 Filed 11–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0326]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 4, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002 (OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (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 conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program.

FDA has a guidance document that provides information for those interested in participating in this 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.''

In the **Federal Register** of August 24, 2006 (71 FR 50067), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents are expected to be businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Information Collection	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation	3	1	3	80	240
Total Hours					240

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

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

Dated: October 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18603 Filed 11–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 016

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: 016'' (Recognition List Number: 016), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

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

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 016'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological

Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Web 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: 016 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, 12720 Twinbrook Pkwy., Rockville, MD 20857, 301–827–0021.

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 a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

FDA has modified its initial list of recognized standards in the following **Federal Register** notices:

TABLE 1.

Federal Register Cite
October 16, 1998 (63 FR 55617)
July 12, 1999 (64 FR 37546)
November 15, 2000 (65 FR 69022)
May 7, 2001 (66 FR 23032)
January 14, 2002 (67 FR 1774)
October 2, 2002 (67 FR 61893)
April 28, 2003 (68 FR 22391)
March 8, 2004 (69 FR 10712)
June 18, 2004 (69 FR 34176)
October 4, 2004 (69 FR 59240)
May 27, 2005 (70 FR 30756)
November 8, 2005 (70 FR 67713)
March 31, 2006 (71 FR 16313)
June 23, 2006 (71 FR 36121)

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains ''hypertext markup language'' (HTML) and ''portable document format'' (PDF) versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the agency's Web site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 016

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: 016'' to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

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

TABLE 2.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
39	CGA V–5: 2005, Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)	Withdrawn and replaced with newer version	68
53	ASTM F1464–93 (2005), Standard Specification for Oxygen Concentrators for Domiciliary Use	Withdrawn and replaced with newer version	69
65	ISO 21647: 2005, Medical Electrical Equipment—Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	Devices affected, Code of Federal Regulations citation, and relevant guidance	
B. Biocompatibility			
107	ASTM F1877–05, Standard Practice for Characterization of Particles	Withdrawn and replaced with newer version	114
108	ASTM F1905–98 (2003), Standard Practice for Selecting Tests for Determining the Propensity of Materials for Cause Immunotoxicity	Title	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
C. Dental/Ear, Nose, and Throat (ENT)			
49	ANSI/ADA Specification No. 17: 1983 (R1999), Denture Base Temporary Relining Resins	Withdrawn and replaced with newer version	130
64	ISO 3107: 2004, Dental Zinc Oxide/Eugenol Cements and Zinc Oxide Non-Eugenol Cements	Withdrawn and replaced with newer version	131
66	ISO 4049: 1988, Dentistry—Resin-Based Filling Materials	Withdrawn. Refer to item no. 99	
70	ISO 6874: 2005, Dental Resin-Based Pit and Fissure Sealants	Withdrawn and replaced with newer version	132
71	ISO 6876: 2001, Dental Root Canal Sealing Materials	Withdrawn and replaced with newer version	133
74	ISO 7494–1: 2004, Dentistry—Dental Units—Part 1: General Requirements and Test Methods	Withdrawn and replaced with newer version	134
114	ANSI/ADA Specification No. 48: 1989, Visible Curing Units	Title	
116	ISO 10139–1: 2005, Dentistry—Soft Lining Materials for Removable Dentures—Part 1: Materials for Short-Term Use	Withdrawn and replaced with newer version	135
D. General Hospital/General Plastic Surgery			
83	ASTM D6319–00a (2005), Standard Specification for Nitrile Examination Gloves for Medical Application	Withdrawn and replaced with newer version	167
87	ASTM D3577–06, Standard Specification for Rubber Surgical Gloves	Withdrawn and replaced with newer version	168
106	ASTM D3772–01 (2005), Standard Specification for Natural Rubber Finger Cots	Withdrawn and replaced with newer version	169
E. In Vitro Diagnostics			
003	CLSI/NCCLS GP10–A 1995, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline	Contact person	
004	CLSI/NCCLS GP14–A 1996, Labeling of Home-Use In Vitro Testing Products; Approved Guideline	Contact person	
007	CLSI/NCCLS LA1–A2 1994, Assessing the Quality of Radioimmunoassay Systems—2d ed.; Approved Guideline	Contact person	
012	CLSI/NCCLS C12–A, Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard	Contact person	
013	CLSI/NCCLS C21–A, Performance Characteristics for Devices Measuring PO2 and PCO2 in Blood Samples; Approved Standard	Contact person	
015	CLSI/NCCLS C25–A, Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline	Contact person	
016	CLSI/NCCLS C27–A, Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline	Contact person	
018	CLSI/NCCLS C30–A, Ancillary (Bedside) Blood Glucose Testing	Contact person	
038	CLSI/NCCLS I/LA10–A, Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline	Contact person	
039	CLSI/NCCLS I/LA17–A, Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline	Contact person	

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
043	CLSI/NCCLS LA4–A3, Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard—3d ed.	Contact person	
048	CLSI/NCCLS T/DM6–A, Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline	Contact person	
051	CLSI/NCCLS GP 27–A, Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline	Contact person	
052	CLSI/NCCLS NRSCL 8–A, Terminology and Definitions for Use in National Committee for Clinical Laboratory Standards (NCCLS) Documents; Approved Standard	Contact person	
055	CLSI/NCCLS H18–A2, Procedures for the Handling and Processing of Blood Specimens; Approved Guideline	Contact person	
059	CLSI/NCCLS AUTO2–A, Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard	Contact person	
F. Materials			
40	ASTM F2063–05, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	Withdrawn and replaced with newer version	122
48	ASTM F899–02, Standard Specification for Stainless Steel for Surgical Instruments	Contact person	
60	ISO 5832–5: 2005, Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy	Withdrawn and replaced with newer version	123
65	ISO 5834–2: 2006, Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 2: Moulded Forms	Withdrawn and replaced with newer version	127
67	ISO 7153–1: 1991/Amd. 1: 1999, Surgical Instruments—Metallic Materials—Part 1: Stainless Steel	Contact person	
70	ASTM F2052–06e1, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Withdrawn and replaced with newer version	124
72	ASTM F2213–06, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment	Withdrawn and replaced with newer version	128
85	ASTM F1854–01, Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants	Contact person	
86	ASTM F1926–03, Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings	Contact person	
88	ASTM F2024–00, Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	Contact person	
89	ASTM F1873–98, Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications	Contact person	
94	ASTM F601–03, Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Contact person	
99	ASTM F2004–05, Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis	Withdrawn and replaced with newer version	125
103	ASTM F1801–97 (2004), Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	Contact person	
106	ASTM F648–04, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Contact person	
109	ASTM F561–05a, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids	Withdrawn and replaced with newer version	126

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
111	ASTM F1160–05, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Contact person	
112	ASTM F1044–05, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Contact person	
113	ASTM F1147–05, Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Contact person	
117	ASTM F86–04, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Contact person	
G. Obstetrics-Gynecology (OB-GYN)/Gastroenterology			
28	ANSI/AAMI RD16: 1996/A1: 2002/(R)2005, Hemodialyzers	Reaffirmation	
29	ANSI/AAMI RD17: 1994/A1: 2002/(R)2005, Hemodialyzer Blood Tubing	Reaffirmation	
31	ANSI/AAMI ID54: 1996/(R)2005, Enteral Feeding Set Adapters and Connectors	Reaffirmation	
H. Ophthalmic			
20	ISO 11979–1: 1999, Ophthalmic Implants—Intraocular Lenses—Part 1: Vocabulary	Contact person	
22	ISO 11979–3: 1999, Ophthalmic Implants—Intraocular Lenses—Part 3: Mechanical Properties and Test Methods	Contact person	
32	ISO 11990: 2003, Optics and Optical Instruments—Lasers and Laser-Related Equipment—Determination of Laser Resistance of Tracheal Tube Shafts	Withdrawn and transferred to Radiology	
I. Orthopedic/Physical Medicine			
85	ISO 14630: 2005, Non-Active Surgical Implants—General Requirements	Withdrawn and replaced with newer version	194
141	ASTM F1612–95 (2005), Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components With Torsion	Withdrawn and replaced with newer version	195
142	ASTM F1672–95 (2005), Standard Specification for Resurfacing Patellar Prosthesis	Withdrawn and replaced with newer version	196
150	ASTM F983–86 (2005), Standard Practice for Permanent Marking of Orthopaedic Implant Components	Withdrawn and replaced with newer version	197
162	ASTM F564–02 (2006), Standard Specification and Test Methods for Metallic Bone Staples	Withdrawn and replaced with newer version	201
174	ASTM F382–99 (2003) e1, Standard Specification and Test Method for Metallic Bone Plates	Withdrawn and replaced with newer version	198
176	ASTM F565–04, Standard Practice for Care and Handling of Orthopedic Implants and Instruments	Withdrawn and replaced with newer version	199
193	ASTM F2083–06, Standard Specification for Total Knee Prosthesis	Withdrawn and replaced with newer version	200
J. Radiology			
32 (Opthalmic)	ISO 11990: 2003, Optics and Optical Instruments—Lasers and Laser-Related Equipment—Determination of Laser Resistance of Tracheal Tube Shafts	Transferred from Ophthalmic, type of standard, and contact person	144
92	IEC 61674 (1997–10), Medical Electrical Cquipment—Dosimeters With Ionization Chambers and/or Semi-Conductor Detectors as Used in X-Ray Diagnostic Imaging	Withdrawn and replaced	145

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
93	IEC 61674 (2002), Amendment 1, Medical Electrical Equipment—Dosimeters With Ionization Chambers and/or Semi-Conductor Detectors as Used in X-Ray Diagnostic Imaging	Withdrawn and replaced	145
118	IEC 60601–2–17 (2005), Medical Electrical Equipment—Part 2–17: Particular Requirements for the Safety of Automatically-Controlled Brachytherapy Afterloading Equipment	Withdrawn and replaced with newer version	146
135	IEC 60601–2–5 (2005), Medical Electrical Equipment—Part 2–5: Particular Requirements for the Safety of Ultrasonic Physiotherapy Equipment ed. 2.0	Withdrawn and replaced with newer version	147
8	IEC 60336 (2005), Medical Electrical Equipment—X-Ray Tube Assemblies for Medical Diagnosis—Characteristics of Focal Spots	Withdrawn and replaced with newer version	149
K. Sterility			
74	ANSI/AAMI ST 60: 1996, Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements	Withdrawn	
103	ISO 11607–2000, Packaging for Terminally Sterilized Medical Devices	Withdrawn	

III. 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: 016, follows:

TABLE 3.

Item No.	Title of Standard	Reference No. and Date
A. Dental/ENT		
136	Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices	ASTM F2504–05
B. General Hospital/General Plastic Surgery		
160	Sterile Single-Use Syringes, With or Without Needle, for Insulin	ISO 8537: 1991/Amendment 1: 2000
161	Sterile, Single-Use Intravascular Catheters—Part 1: General Requirements	ISO 10555–1: 1996/Amendment 1: 1999, Amendment 2: 2004
162	Infusion Equipment for Medical Use—Part 1: Infusion Glass Bottles	ISO 8536–1: 2000/Amendment 1: 2004
163	Stainless Steel Needle Tubing for the Manufacture of Medical Devices	ISO 9626: 1991/Amendment 1: 2001
164	Sterile, Single-Use Intravascular Catheters—Part 5: Over-Needle Peripheral Catheters	ISO 10555–5: 1996/Amendment 1: 1999, Corrigendum 1: 2002
165	Standard Specification for Polychloroprene Examination Gloves for Medical Application	ASTM D6977–04
166	Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps	ASTM F2132–01
C. In Vitro Diagnostics		
124	Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline	CLSI/NCCLS I/LA24–A
125	Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline	CLSI M28–A2, Vol. 25, No. 16
126	Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes	CLSI M24–A, Vol. 23, No. 18
D. OB-GYN/Gastroenterology		

TABLE 3.—Continued

Item No.	Title of Standard	Reference No. and Date
38	Optics and Optical Instruments—Medical Endoscopes and Endoscopic Accessories Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics	ISO 8600–3: 1997/Amendment 1: 2003
39	Optics and Photonics—Medical Endoscopes and Endotherapy Devices—Part 5: Determination of Optical Resolution of Rigid Endoscopes with Optics	ISO 8600–5: 2005
40	Optics and Photonics—Medical Endoscopes and Endotherapy Devices—Part 6: Vocabulary	ISO 8600–6: 2005
E. Radiology		
145	Medical Electrical Equipment—Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as Used in X-Ray Diagnostic Imaging	IEC 61674 (1997), (2002), Amendment 1
148	Medical Electrical Equipment—Part 2–37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment	IEC 60601–2–37 (2005), Amendment 2
F. Software		
8	Medical Device Software—Software Life Cycle Processes	IEC 62304 ed. 1.0 (2006)
G. Sterility		
193	Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems, 3d ed.	ANSI/AAMI/ISO 11607–1: 2006
194	Packaging for Terminally Sterilized Medical Devices—Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes, 1st ed.	ANSI/AAMI/ISO 11607–2: 2006
195	Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements, 2d ed.	ANSI/AAMI/ISO 11140–1: 2005

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

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 016'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

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

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

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 016. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: October 27, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–18604 Filed 11–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Extension

Section 602 of Pub. L. 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit Guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA OPA for review. The office will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute Resolution Guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA OPA has developed an informal dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA OPA, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

The estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Audits					
Audit Notification of Entity*	2	1	2	4	8
Audit Work Plan	1	1	1	8	8
Audit Report	1	1	1	1	1
Entity Response	0	0	0	0	0
Dispute Resolution					
Mediation Request	2	4	8	10	80
Rebuttal	2	1	2	16	32
Total Reporting	8		14		129
Recordkeeping Requirement					
Dispute Records	10	1	10	.5	5
Total Recordkeeping	10				5

* Prepared by the manufacturer.