INA 412(c)(1)(B) states that formula funds shall be allocated based on the total number of refugees, taking into account secondary migration.

In order to meet the statutory requirements, ORR requires each state to submit disaggregated individual records containing certain data elements for eligible refugee populations. This revised collection differs from the ORR–11 Refugee State-of-Origin Report process, whereby states submitted the ORR–11 form containing aggregate data on the number of refugees and entrants served whose ''area numbers'' (the first three digits of the social security number) fell into each of several designated numerical ranges. ORR used the information on the ORR–11 to measure secondary migration for the purposes of formula funds allocation to states. The revision is proposed due to the realization that:

(1) The Social Security Administration states that the first three digits of social security numbers (area number) should not be used for any other purpose than as an individual identifier for book-keeping purposes.

(2) It is possible for individuals to apply for Social Security Numbers from any Social Security office, not just offices in the state in which they were born or first resided. This is particularly likely in metropolitan statistical areas where individuals may live in one of several states (e.g., the Washington Metropolitan Area). In these cases, the area number of the Social Security Number may be unreliable as a measure of refugees' state of initial resettlement.

(3) In recent years, the Social Security Administration has begun to issue Social Security Numbers whose area number is not connected to any specific state.

The submission of individual records via the Refugee Data Submission System for Formula Funds Allocations Web site is a more reliable and secure process for collecting data for the purposes of tracking secondary migration and allocating formula funds. Data submitted by the States via the secure Web site are compiled and analyzed by the ORR statistician for the purpose of refugee secondary services formula funds allocation. The statistician also prepares a summary report, which is included in ORR's Annual Report to Congress.

Respondents: States and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Data Submission for Formula Funds Allocations	50	1	20	1,000

Estimated Total Annual Burden Hours: 1,000.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project.

Fax: 202–395–6974.

Attn: Desk Officer for the Administration for Children and Families.

Dated: March 13, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–5814 Filed 3–17–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 021

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: 021'' (Recognition List Number: 021), 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: 021'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 240–276–3151. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 021 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, 7520 Standish Place, Rockville, MD 20855, 240–276–8714.

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.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, are identified in table 1.

TABLE 1—FEDERAL REGISTER CITATION

October 16, 1998 (63 FR 55617)	May 27, 2005 (70 FR 30756)
July 12, 1999 (64 FR 37546)	November 8, 2005 (70 FR 67713)
November 15, 2000 (65 FR 69022)	March 31, 2006 (71 FR 16313)
May 7, 2001 (66 FR 23032)	June 23, 2006 (71 FR 36121)
January 14, 2002 (67 FR 1774)	November 3, 2006 (71 FR 64718)
October 2, 2002 (67 FR 61893)	May 21, 2007 (72 FR 28500)
April 28, 2003 (68 FR 22391)	September 12, 2007 (72 FR 52142)
March 8, 2004 (69 FR 10712)	December 19, 2007 (72 FR 71924)
June 18, 2004 (69 FR 34176)	September 9, 2008 (73 FR 52358)
October 4, 2004 (69 FR 59240)	

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

II. Modifications to the List of Recognized Standards, Recognition List Number: 021

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: 021'' to identify these current modifications.

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

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

TABLE 2

Old Recognition No.	Replacement Recognition No.	Standard	Change
A. Anesthesia			
1–49		ASTM F 1981–99 Standard Specification for Suction Catheters for use in the Respiratory Tract	Withdrawn
1–63	1–77	CGA V–1:2005 Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connection	Withdrawn and replaced with newer version
1–64	1–78	ASME PVHO–1–2007 Safety Standard for Pressure Vessels for Human Occupancy	Withdrawn and replaced with newer version

TABLE 2—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
1–71		ISO 10651–5:2006 Lung Ventilators for Medical Use—Particular requirements for Basic Safety and Essential Performance—Part 5: Gas-powered Emergency Resuscitators	Withdrawn duplicate
1–74		ISO 5360:2006 Anaesthetic Vaporizers—Agent Specific Filling Systems	Contact person
1–76	1–79	ISO 26825:2008 (E) Anaesthetic And Respiratory Equipment—User-Applied Labels For Syringes Containing Drugs Used During Anaesthesia—Colours, Design and Performance	Withdrawn and replaced with newer version
B. Biocompatibility			
2–71	2–133	ASTM F1408–97 (2008) Standard Practice for Subcutaneous Screening Test for Implant Materials	Withdrawn and replaced with newer version
2–73	2–134	ASTM F2065–00(2006) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Withdrawn and replaced with newer version
2–87		AAMI/ANSI/ISO 10993–10:2002 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	Extent of Recognition, Relevant Guidance, and Contact Person
2–88	2–135	AAMI/ANSI/ISO 10993–12:2007 Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials	Withdrawn and replaced with newer version
2–127		ANSI/AAMI BE 78:2002/A1:2006 Biological Evaluation of Medical Devices—Part 10: Tests For Irritation and Delayed-Type Hypersensitivity—Amendment 1	Withdrawn
C. Cardiovascular/Neurology			
3–67		ASTM F2129–06 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Offices, Devices Affected, Relevant Guidance, CFR Citation and Product Codes, Contact Person
D. General Hospital/General Plastic Surgery			
6–29		IEC 60601–2–19 1996–10: Amendment 1—Medical Electrical Equipment Part 2: Particular Requirements for Safety of Baby Incubators	Relevant guidance
6–32		IEC 60601–2–20 1996–10: Amendment 1—Medical Electrical Equipment Part 2: Particular Requirements for the Safety Of Transport Incubators	Relevant guidance
6–62		ISO 8536–6:1995 Infusion Equipment for Medical Use—Part 6: Freeze Drying Closures for Infusion Bottles	Relevant guidance
6–63		ISO 8536–7–1999: Infusion Equipment for Medical Use—Part 7: Caps Made of Aluminum-Plastics Combinations For Infusion Bottles	Relevant guidance
6–64		ISO 8536–3–1999, Infusion Equipment for Medical Use—Part 3: Aluminum Caps for Infusion Bottles	Relevant guidance
6–119		ANSI/AAMI BF7:1989/(R)2002/(R)2007 Blood Transfusion Micro-Filters	Reaffirmation 2007, Title, SDO, Date of standard, Relevant guidance
6–122		ISO 8536–5–2004:, Infusion Equipment for Medical Use—Part 5: Burette Infusion Sets for Single Use, Gravity Feed	Relevant guidance
6–127		ISO 1135–4–2004: Transfusion Equipment for Medical Use—Part 4: Transfusion Sets for Single Use	Relevant guidance
6–142		ANSI/AAMI II36:2004 Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Baby Incubators	Title, Relevant guidance
6–143		ANSI/AAMI II51:2004, Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Transport Incubators	Title, Relevant guidance

TABLE 2—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
6–172		ISO 8536–1:2006 Infusion Equipment for Medical Use—Part 1: Infusion Glass Bottles	Relevant guidance
6–173		ISO 8536–2:2001 Corrigendum 1:2003, Infusion Equipment for Medical Use—Part 2: Closures for Infusion Bottles	Relevant guidance
6–182		IEC 60601–2–38 1996/Amendment 1:1999, Medical Electrical Equipment—Part 2–38: Particular Requirements for the Safety of Electrically Operated Hospital Beds	Relevant guidance
6–201		ISO 8536–4:2007 Infusion Equipment for Medical Use—Part 4: Infusion Sets for Single Use, Gravity Feed	Relevant guidance
6–215		ASTM F2132–01(2008)E1 Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps	Title
E. IVD			
7–138	7–169	CLSI M27–A3 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts	Withdrawn and replaced with newer version
7–54		CLSI D12–A2, Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials—Second Edition; Approved Guideline	Title
7–71		CLSI H15–A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition	Contact person
7–145		CLSI H42–A2, Enumeration of Immunologically Defined Cell Populations by Flow Cytometry.	Contact person
7–73	7–170	CLSI ILA21–A2 Clinical Evaluation of Immunoassays	Withdrawn and replaced with newer version
7–130		CLSI H20–A2, Reference Leucocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition	Contact person
7–164		CLSI GP 28–A Microwave Device Use in the Histology Laboratory; Approved Guideline	Contact person
7–168	7–171	CLSI M38–A2 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi	Withdrawn and replaced with newer version
F. Neurology			
3–3	17–1	AAMI NS28:1988/(R) 2006 Intracranial Pressure Monitoring Devices	Transferred, Date of standard, Extent of recognition, Relevant guidance
3–32	17–2	ASTM F1542–94(2000) Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips	Transferred, Offices, Type of standard, Extent of recognition, Relevant guidance, Contact person
3–33	17–3	ISO 7197:2006 Neurosurgical implants—Sterile, Single-use hydrocephalus Shunts and Components	Transferred—Withdrawn and replaced with newer version
3–39	17–4	ASTM F647–94(2006) Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	Transferred—Withdrawn and replaced with newer version
3–60	17–5	IEC 60601–2–10 1987/Amendment 1 2001 Medical Electrical Equipment—Part 2–10: Particular Requirements for the Safety of Nerve and Muscle Stimulators	Transferred, Title change, Date of standard, Relevant guidance, Contact person
3–67	17–6	ASTM F2129–06 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Offices, Devices affected, Type of Standard, Product code, Relevant guidance, Contact person
G. OB-GYN/Gastroenterology			

TABLE 2—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
9–30	9–55	ANSI/ AAMI RD62:2006 Water Treatment Equipment for Hemodialysis Applications	Withdrawn and replaced with newer version
9–32	9–56	ASTM D3492–08 Standard Specification for Rubber Contraceptives (Male Condoms)	Withdrawn and replaced with newer version
9–34		ISO 4074:2002/Cor.1:2003(E): Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 1	Extent of recognition, Product codes, Relevant guidance
H. Radiology			
12–48		AIUM AOL, Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data	Relevant guidance
12–55	12–186	IEC 60601–2–29 (2008) Medical Electrical Equipment—Part 2–29: Particular Requirements for the Basic Safety and Essential Performance of Radiotherapy Simulators—Third Edition	Withdrawn and replaced with newer version
12–66		AIUM MUS, Medical Ultrasound Safety	Relevant guidance
12–96	12–187	NEMA MS 3–2008 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images	Withdrawn and replaced with newer version
12–97	12–188	NEMA MS 1–2008 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging	Withdrawn and replaced with newer version
12–100		NEMA UD 3–2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	Relevant guidance
12–105		NEMA UD 2–2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3	Title, Relevant guidance
12–139		AIUM AOMS–2005, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Relevant guidance
12–140		AIUM RTD1–2005, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1	Relevant guidance
12–161	12–189	IEC 60601–2–33 (2008) Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis Consolidated Edition 2.2	Withdrawn and replaced with a newer version
12–182		IEC 60601–2–37:2007, Medical Electrical Equipment—Part 2–37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	Relevant guidance
12–184	12–190	IEC 61217 (2008) Radiotherapy Equipment—Coordinates, Movements, and Scales Consolidated Edition 1.2	Withdrawn and replaced with newer version
I. Sterility			
14–120	14–257	ASTM D3078—02(2008) Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Withdrawn and replaced with newer version
14–148	14–258	ASTM F2250—03(2008) Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	Withdrawn and replaced with newer version
14–149	14–259	ASTM F2251—03(2008) Standard Test Method for Thickness Measurement of Flexible Packaging Material	Withdrawn and replaced with newer version
14–150	14–260	ASTM F2252—03(2008) Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	Withdrawn and replaced with newer version
J. Tissue Engineering			
15–11	15–13	ASTM F2212–02(2008)e1, Standard Guide for Characterization of Type I Collagen as a Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products	Withdrawn and replaced with newer version

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 021.

TABLE 3

Recognition No.	Title of Standard	Reference No. & Date
A. Dental/ENT		
4–160	Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms	ANSI ASA S3.1–1999 (R 2003)
4–161	Method for Measuring the Intelligibility of Speech Over Communication Systems	ANSI ASA S3.2–1989 (R 1999)
4–162	Procedure for the Computation of Loudness of Steady Sounds	ANSI ASA S3.4–2007
4–163	Methods for Calculation of the Speech Intelligibility Index	ANSI ASA S3.5–1997 (R 2007)
4–164	Method for Coupler Calibration of Earphones	ANSI ASA S3.7–1995 (R 2003)
4–165	Mechanical Coupler for Measurement of Bone Vibrators	ANSI ASA S3.13–1987 (R 2007)
4–166	Bioacoustical Terminology	ANSI ASA S3.20–1995 (R 2003)
4–167	Methods for Manual Pure-Tone Threshold Audiometry	ANSI ASA S3.21–2004
4–168	Occluded Ear Simulator	ANSI ASA S3.25–1989 (R 2003)
4–169	Method of Measurement of Performance Characteristics of Hearing Aids under Simulated Real-Ear Working Conditions	ANSI ASA S3.35–2004
4–170	Specification for a Manikin for Simulated *in situ* Airborne Acoustic Measurements	ANSI ASA S3.36–1985 (R 2006)
4–171	Preferred Earhook Nozzle Thread for Postauricular Hearing Aids	ANSI ASA S3.37–1987 (R 2007)
4–172	Testing Hearing Aids with a Broad-Band Noise Signal	ANSI ASA S3.42–1992 (R 2007)
4–173	Determination of Occupational Noise Exposure and Estimation of Noise-Induced Hearing Impairment	ANSI ASA S3.44–1996 (R 2006)
4–174	Procedures for Testing Basic Vestibular Function	ANSI ASA S3.45–1999
4–175	Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids	ANSI ASA S3.46–1997 (R 2002)
4–176	Criteria for Evaluating Room Noise	ANSI ASA S12.2–1995 (R 1999)
4–177	Rating Noise with Respect to Speech Interference	ANSI ASA S12.65–2006
B. General		
5–45	Standard Practice for Performance Testing of Packages for Single Delivery Systems	ASTM D7386–08
C. IVD		
7–172	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory	C28–P3
7–173	Harmonization of Glycohemoglobin Measurements	C44–A
7–174	Estimation of Total Analytical Error for Clinical Laboratory	EP21–A
7–175	Apolipoprotein Immunoassays: Development and Recommended Performance Characteristics	ILA15–A
7–176	Immunoassay Interference by Endogenous Antibodies	ILA30–A

TABLE 3—Continued

Recognition No.	Title of Standard	Reference No. & Date
7–177	Performance Standards for Antimicrobial Susceptibility Testing	M100–S18
7–178	Quality Control for Commercially Prepared Microbiological Culture Media	M22–A3
7–179	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts	M27–S3
7–180	Western Blot Assay for Antibodies to Borrelia burgdorferi	M34–A
7–181	Abbreviated Identification of Bacteria and Yeasts	M35–A
7–182	Clinical Use and Interpretation of Serologic Tests for Toxoplasma gondii	M36–A
7–183	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi	M38–A2
7–184	Quality Control of Microbiological Transport Systems	M40–A
7–185	Viral Culture	M41–A
7–186	Methods for Antifungal Disk Diffusion Susceptibility Testing	M44–A
7–187	Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeast	M44–S2
7–188	Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria	M45–A
7–189	Principles and Procedures for Blood Cultures	M47–A
7–190	Quality Control for Commercial Microbial Identification Systems	M50–A
7–191	Collection, Transport, Preparation, and Storage of Specimens	MM13–A
7–192	Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing	MM18–A
7–193	Evaluation of the Linearity of Quantitative Measurement	EP06–A
7–194	Protocols for Determination of Limits of Detection and Limits of Quantitation	EP17–A
D. Neurology		
17–7	Neurosurgical implants—Sterile, Single-use Hydrocephalus Shunts and Components	ISO 7197:2006/Technical Corrigendum1:2007
E. OB-GYN/Gastroenterology		
9–57	Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 2	ISO 4074:2002/Cor.2:2008(E)
F. Ophthalmic		
10–58	Laser Systems for Corneal Reshaping	ANSI Z80.11–2007
G. Radiology		
12–191	Ultrasonics—Field Characterization—Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields	IEC 62359:2005
H. Software/Informatic		
13–25	Managing and Validating Laboratory Information Systems; Approved Guideline	CLSI AUTO8–A
13–26	Autoverification of Clinical Laboratory Test Results; Approved Guideline	CLSI AUTO10–A
13–27	IT Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard	CLSI AUTO11–A
13–28	Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard	CLSI AUTO9–A
I. Sterility		
14–261	Sterilization of Health Care Products—Moist Heat—Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	ANSI/AAMI/ISO 17665–1:2006

IV. List of Recognized Standards

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

V. Recommendation of Standards for Recognition by FDA

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

VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this document announcing ''Modification to the List of Recognized Standards, Recognition List Number: 021'' 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. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 021. These modifications to the list or recognized standards are effective upon publication of this document in the **Federal Register**.

Dated: March 10, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E9–5858 Filed 3–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase VI—NEW.

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center of Mental Health Services is responsible for the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (Children's Mental Health Initiative—CMHI) that will collect data on child mental health outcomes, family life, and service system development and performance. Data will be collected on 26 service systems, and approximately 5,541 children and families.

Data collection for this evaluation will be conducted over a five-year period. Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The length of time that individual families will participate in the study ranges from 12 to 24 months depending upon when they enter the evaluation. The outcome measures include the following: Child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The core of service system data will be collected every 18–24 months throughout the 5-year evaluation period, with a sustainability survey conducted in years 3 and 5. Service utilization and cost data will be tracked and submitted to the national evaluation every six months using two tools: The Flex Fund Tool and the Services and Costs Data Tool to estimate average cost of treatment per child, distribution of costs, and allocation of costs across service categories. Service delivery and system variables of interest include the following: Maturity of system of care development in funded system of care communities, adherence to the system of care program model, and client service experience. We will also conduct a comprehensive evaluation of the CMHI's data driven technical assistance; this component of the evaluation will employ a mixed-methods approach, combining qualitative and quantitative data to provide a comprehensive assessment of the continuous quality improvement (CQI) process in funded system of care