

presentations from the public will be scheduled between approximately 8:35 a.m. and 9 a.m., 11 a.m. and 11:30 a.m., 2 p.m. and 2:30 p.m., and 4:30 p.m. and 5 p.m. on July 22, 2004; and between approximately 10:15 a.m. and 11:15 a.m. and 2 p.m. and 2:30 p.m. on July 23, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 12, 2004, 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.

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 Linda A. Smallwood, or Pearline K. Muckelvene at 301-827-1281 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: June 14, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-13727 Filed 6-17-04; 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 July 13, 2004, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom Salons A and B, 620 Perry Pkwy., 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, 301-827-5283, ext. 123, e-mail: mea@cdrh.fda.gov, or FDA Advisory Committee Information Line 800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a bone grafting material, which contains a wound-healing and revascularization agent, for treatment of dental osseous defects. 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/panel/index.html>. Material will be posted on July 12, 2004.

Procedure: On July 13, 2004, from 8:30 a.m. to 5 p.m., the meeting is open to the public. 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 July 1, 2004. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 1, 2004, 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 July 13, 2004, from 8 a.m. to 8:30 a.m., the meeting will be closed 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: June 14, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-13726 Filed 6-17-04; 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: 010

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 of the List of Recognized Standards, Recognition List Number: 010" (Recognition List Number: 010), 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: 010" to the Division of Small Manufacturers 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 to recommend 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.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: 010 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 a guidance document 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), October 2, 2002 (67 FR 61893), April 28, 2003 (68 FR 22391), and March 8, 2004 (69 FR 10712), 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 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: 010

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: 010" to identify these current modifications.

In the following table, FDA describes modifications that involve: (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.

A. Anesthesia

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|--|----------------------|
| 19 | ISO 8382:1988, Resuscitators Intended for Use with Humans | Processes impacted, extent of recognition, relevant guidance | 19 |
| 42 | ISO 5360:1993, Anaesthetic vaporizers—Agent-specific filling systems | Devices affected, processes impacted, extent of recognition | 42 |

B. General

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|---------------------------|----------------------|
| 2 | IEC 60601–1, Medical Electrical Equipment—Part 1: General Requirements for Safety | Contact person | 2 |
| 28 | IEC 60601–1–2 (Second Edition, 2001) Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests | Contact person | 28 |
| 30 | ANSI/AAMI/IEC 60601–1–2:2001, Medical Electrical Equipment—Parts 1 to 2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests | Correct title of standard | 30 |

C. General Hospital/General Plastic Surgery

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|---|---|----------------------|
| 3 | ASTM F754–88, Standard Specification for Implantable Poly-tetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube and Rod Shapes | Withdrawn and replaced with new version | 108 |
| 4 | ASTM F881–94, Standard Specification for Elastomer Facial Implants | Withdrawn and replaced with newer version | 109 |
| 6 | ASTM F1441–92, Standard Specification for Soft Tissue Expanders | Withdrawn and replaced with newer version | 110 |
| 10 | IEC 60601–2–38, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds | Withdrawn and replaced with newer version | 111 |

D. In Vitro Diagnostic

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|---|----------------------|
| 47 | NCCLS MM2–A2 Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline—Second Edition | Withdrawn and replaced with newer version | 98 |
| 84 | CEN 13640, Stability Testing of In Vitro Diagnostic Reagents | Correction to date of standard | 84 |

E. Materials

| Old Item No. | Title of Standard | Change | Replacement Item No. |
|--------------|--|--|----------------------|
| 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) | Title change | 26 |
| 39 | ASTM F2052–02, Standard Test Method for Measurement of Magnetically Induced Displacement Force on medical Devices in the Magnetic Resonance Environment | Recognizing a newer version with a revised title | 70 |
| 55 | ASTM F2182–02a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging | Recognizing a newer version | 71 |
| 62 | ISO 5832–1:1997, Implants for Surgery—Metallic materials—Part 1: Wrought stainless steel | Transferred from Orthopedics 62 to Materials 56 | 56 |
| 64 | ISO 5832–3:1996, Implants for Surgery—Metallic materials—Part 3: Wrought titanium 6-aluminum 4-vanadium alloy | Transferred from Orthopedics 64 to Materials 58 | 58 |
| 65 | ISO 5832–4:1996, Implants for Surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy | Transferred from Orthopedics 65 to Materials 59 | 59 |
| 62 | ISO 5832–1:1997, Implants for Surgery—Metallic materials—Part 1: Wrought stainless steel | Transferred from Orthopedics 62 to Materials 56 | 56 |
| 64 | ISO 5832–3:1996, Implants for Surgery—Metallic materials—Part 3: Wrought titanium 6-aluminum 4-vanadium alloy | Transferred from Orthopedics 64 to Materials 58 | 58 |
| 65 | ISO 5832–4:1996, Implants for Surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy | Transferred from Orthopedics 65 to Materials 59 | 59 |
| 66 | ISO 5832–5:1993, Implants for Surgery—Metallic materials—Part 5: Wrought cobalt-chromium-tungsten-nickel alloy | Transferred from Orthopedics 66 to Materials 60 | 60 |
| 67 | ISO 5832–6:1997, Implants for Surgery—Metallic materials—Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy | Transferred from Orthopedics 67 to Materials 61 | 61 |
| 70 | ISO 5832–11:1994, Implants for Surgery—Metallic materials—Part 11: Wrought titanium 6-aluminum 7-niobium alloy | Transferred from Orthopedics 70 to Materials 63 | 63 |

| Old Item No. | Title of Standard | Change | Replacement Item No. |
|--------------|--|--|----------------------|
| 71 | ISO 5832-12:1996, Implants for Surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy | Transferred from Orthopedics 71 to Materials 64 | 64 |
| 76 | ISO 6474-94, Implants for surgery—Ceramic materials based on high purity alumina | Transferred from Orthopedics 76 to Materials 66 | 66 |
| 84 | ISO 13782:1996, Implants for surgery—Metallic materials—Unalloyed tantalum for surgical implant applications | Transferred from Orthopedics 84 to Materials 68 | 68 |
| 117 | ISO 5832-2:1999, Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium | Transferred from Orthopedics 117 to Materials 57 | 57 |
| 118 | ISO 5832-9:1992, Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel | Transferred from Orthopedics 118 to Materials 62 | 62 |
| 119 | ISO 5834-2:1998, Implants for Surgery—Ultra-High-Molecular Weight Polyethylene—Part 2: Moulded Forms | Transferred from Orthopedics 119 to Materials 65 | 65 |
| 143 | ISO 7153-1:1991/Amd. 1:1999, Surgical instruments—Metallic materials—Part 1: Stainless steel | Transferred from Orthopedics 143 to Materials 67 | 67 |

F. Radiology

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|------------------|----------------------|
| 5 | ANSI Ph 2.50-1983, Photography—Direct-Exposing Medical and Dental Radiographic Film/Process Systems—Determination of ISO Speed and Average Gradient | Title correction | 5 |
| 7 | ISO/IEC 10918-1:1994, Information Technology—Digital Compression and Coding of Continuous—Tone Still Images: Requirements and Guidelines | Title correction | 7 |
| 8 | IEC 60336 (R1993), X-ray Tube Assemblies for Medical Diagnosis Characteristics of Focal Spots | Title correction | 8 |
| 17 | NEMA MS 8-1993 (2000), Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems | Reaffirmation | 17 |
| 22 | NEMA XR 5-1992 (R1999), Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-ray Tubes | Reaffirmation | 22 |
| 23 | NEMA XR 10-1986 (R1992, R1998), Measurement of the Maximum Symmetrical Radiation Field from a Rotating Node X-ray Tube used for Medical Diagnosis | Reaffirmation | 23 |
| 24 | NEMA XR 11-1993 (R1999), Test Standard for Determination of the Limiting Spatial Resolution of X-ray Image Intensifier Systems | Title correction | 24 |
| 25 | NEMA XR 15-1991 (R1996, R2001), Test Standard for the Determination of the Visible Entrance Field Size of an X-ray Image Intensifier System | Reaffirmation | 25 |
| 26 | NEMA XR 16-1991 (R1996, R2001), Test Standard for the Determination of the System Contrast Ratio and the System Veiling Glare Index of an X-ray Image Intensifier System | Reaffirmation | 26 |
| 27 | NEMA XR 17-1993 (R1999), Test Standard for the Measurement of the Image Signal Uniformity of an X-ray Image Intensifier System | Reaffirmation | 27 |
| 28 | NEMA XR 18-1993 (R1999), Test Standard for the Determination of the Radial Image Distortion of an X-ray Image Intensifier System | Reaffirmation | 28 |
| 29 | NEMA XR 19-1993 (R1999), Thermal and Loading Characteristics of X-ray Tubes used for Medical Diagnosis | Reaffirmation | 29 |

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|---|----------------------|
| 44 | AIUM AOMS—Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment | Title correction and reaffirmation | 44 |
| 46 | AIUM RTD1—Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1 | Title correction and reaffirmation | 46 |
| 48 | AIUM AOL—Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data | Title correction | 48 |
| 61 | UL 122–1999, Standard for Safety of Photographic Equipment—4th Edition | Title correction | 61 |
| 66 | AIUM MUS—Medical Ultrasound Safety | Title correction and reaffirmation | 66 |
| 72 | NEMA UD 3–1998, Revision 1, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment | Title correction | 72 |
| 11 | NEMA MS 2–2003, Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images | Withdrawn and replaced with newer version | 95 |
| 12 | NEMA MS 3–2003, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images | Withdrawn and replaced with newer version | 96 |
| 77 | NEMA MS–1–2001, Determination of Signal to Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images | Withdrawn and replaced with newer version | 97 |
| 69 | NEMA MS 6–1991 (R2000), Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images | Reaffirmation | 69 |
| 3 | ANSI IT1.49–1995, Photography (Films)—Medical Radiographic Cassettes/Screens/Films-Dimensions | Withdrawn and replaced with Item 98 | |
| 14 | NEMA MS 5–2003, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging | Withdrawn and replaced with newer version | 99 |

G. Sterility

| Old Item No. | Standard | Change | Replacement Item No. |
|--------------|--|--|----------------------|
| 76 | AAMI/ANSI/ISO 10993–7:1995 (R) 2001, Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals | Deleted “Hemodialyzers” from Extent of Recognition | 76 |

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: 010, is as follows:

A. Anesthesia

| Item No. | Title of Standard | Reference No. and Date |
|----------|---|------------------------|
| 47 | Ancillary devices for expired air resuscitation | AS 4259–1995 |
| 48 | Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits | ASTM F1246–91(1999) |
| 49 | Standard Specification for Suction Catheters for Use in the Respiratory Tract | ASTM F1981–99 |

B. General

| Item No. | Title of Standard | Reference No. and Date |
|----------|--|------------------------|
| 33 | Medical Electrical Equipment—Parts 1 to 8: General requirements for safety—Collateral Standard: Alarm systems—Requirements, tests, and guidelines—General requirements and guidelines for alarm systems in medical equipment | IEC 60601-1-8:2003 |

C. In Vitro Diagnostic

| Item No. | Title of Standard | Reference No. and Date |
|----------|---|------------------------|
| 99 | Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline | NCCLS MM5-A:2000 |
| 100 | In Vitro Diagnostic Test Systems—Requirements for In Vitro Whole Blood Glucose Monitoring Systems Intended for Use by Patients for Self Testing in Management of Diabetes Mellitus, First Edition | ISO 15197:2003 |
| 101 | Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline | NCCLS H51-A:2002 |

D. Materials

| Item No. | Title of Standard | Reference No. and Date |
|----------|--|------------------------|
| 72 | Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment | ASTM F2213-04 |

E. Radiology

| Item No. | Title of Standard | Reference No. and Date |
|----------|--|-------------------------------|
| 98 | Medical Electrical Equipment—Dosimeters with Ionization Chambers as Used in Radiotherapy | IEC 60731—Amendment 1 2002-06 |

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 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 "Modification to the List of Recognized Standards, Recognition List Number: 010" 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 hyperlink 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 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: 010." These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: June 2, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-13725 Filed 6-17-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of a Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council on June 30 and July 1, 2004.

The SAMHSA National Advisory Council meeting will be open to the public. The meeting will include the SAMHSA Administrator's Report, and discussions on Mental Health Systems Transformation, the Co-occurring Report, SAMHSA's Strategic Prevention Framework Initiative, suicide prevention, and SAMHSA's Access to Recovery Initiative. The meeting will also include a discussion of the Agency's current legislative highlights, and an update on the Interagency Coordinating Committee on the Prevention of Underage Drinking.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

Substantive program information, a summary of the meeting, and a roster of Council members may be obtained either by accessing the SAMHSA Council Web site, <http://www.samhsa.gov/council/council> or by communicating with the contact whose name and telephone number is listed below. The transcript for the meeting will also be available on the SAMHSA Council Web site.

Committee Name: SAMHSA National Advisory Council.

Date/Time: Wednesday, June 30, 2004, 9 a.m. to 4:45 p.m. (Open), Thursday, July 1, 2004, 9 a.m. to 12:15 p.m. (Open).

Place: Hilton Washington Embassy Row Hotel, Ambassador Room, 2015 Massachusetts Avenue, NW., Washington, DC 20036.

Contact: Toian Vaughn, Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 12C-05, Rockville, MD 20857, Telephone: (301) 443-7016; FAX: (301) 443-1450 and E-mail: tovaughn@samhsa.gov.

Dated: June 14, 2004.

Toian Vaughn,

Committee Management Officer, SAMHSA.
[FR Doc. 04-13791 Filed 6-17-04; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

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

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency has submitted the following proposed information collection to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507).

Title: Federal Emergency Management Agency (FEMA) Mitigation Success Story Database.

Type of Information Collection: Existing collection in use without an OMB Control Number.

OMB Number: OMB No. 1660-NEW6.

Abstract: This Web-based database serves a dual purpose in providing a centralized and user-friendly venue for gaining and disseminating knowledge about effective and efficient mitigation strategies implemented in communities nationwide. By sharing information, communities and individuals can learn about available Federal programs to support implementation of mitigation projects relevant to individual conditions and characteristics.

Affected Public: State, local and tribal governments, individuals, business or other for-profit organizations, not-for

profit institutions, and Federal government.

Number of Respondents: 150.

Estimated Time per Respondent: The electronic submission takes approximately 30 minutes for filling in all fields in the submission form, and approximately 1 hour to conceptualize the narrative description for a total of 1.5 hours. Respondents choosing to supply the information directly to FEMA Regional or HQ staff or to a Disaster Field Office (DFO) staff may spend up to 4 hours, which includes initial interview and follow-up sessions (when needed and agreed upon by the respondent on a voluntary basis).

Estimated Total Annual Burden Hours: 563 hours.

Frequency of Response: One time.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Emergency Preparedness and Response Directorate/Federal Emergency Management Agency, U.S. Department of Homeland Security, 725 17th Street, NW., Docket Library Room 10102, Washington, DC 20503. Comments must be submitted on or before July 19, 2004. In addition, interested persons may also send comments to FEMA (*see* contact information below).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Muriel B. Anderson, Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646-3347, or e-mail address FEMA-Information-Collections@dhs.gov.

Dated: June 9, 2004.

Edward W. Kernan,

Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 04-13776 Filed 6-17-04; 8:45 am]

BILLING CODE 9110-13-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1518-DR]

Iowa; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.