intramuscular injection (210 milligrams (mg), 300 mg, and 405 mg per/vial), Eli Lilly and Co., for the treatment of schizophrenia. A particular safety concern for discussion is the occurrence of severe somnolence in some patients who are administered this depot formulation of olanzapine.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 18, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before January 10, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 11, 2007.

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 Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: December 12, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–24627 Filed 12–18–07; 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: 019

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: 019'' (Recognition List Number: 019), 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: 019'' 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 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: 019 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, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0533.

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 of this document.

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)
November 3, 2006 (71 FR 64718)
May 21, 2007 (72 FR 28500)
September 12, 2007 (72 FR 52142)

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: 019

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: 019 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 Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
11	IEC 60601–3–1:1996–08 Medical Electrical Equipment - Part 3–1: Essential Performance Requirement for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment	Title Change Contact person	
18	ISO 8359:1996 Oxygen Concentrators for Medical Use - Safety Requirements	Contact person	
51	ASTM F1100–90(1997) Standard Specification for Ventilators Intended for Use in Critical Care	Contact person Relevant guidance	
57	ASTM F1101–90(2003)e1 Standard Specification for Ventilators Intended for Use During Anesthesia	Contact person	
59	ASTM F1456-01 Standard Specification for Minimum Performance and Safety Requirements for Capnometers	Relevant guidance	
60	IEC 60601–2–12:(2001–10) Medical Electrical Equipment - Part 2–12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators	Contact person Relevant guidance	
61	IEC 60601-2-13(2003-05):, Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems	Relevant guidance	
65	ISO 21647: 2004 Medical Electrical Equipment - Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	Title Change Relevant guidance	
69	ASTM F1464–93(2005) Standard Specification for Oxygen Concentrators for Domiciliary Use	Contact person	
70	ASTM F 1246–91 (2005) Standard Specification for Electrically Powered Home Care Ventilators, Part 1 - Positive-Pressure Ventilators and Ventilator Circuits	Contact person Relevant guidance	
71	ISO 10651–5:2006 Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas-powered Emergency Resuscitators	Contact person	
B. General			
20	ASTM F1140:1988: Standard Test Method for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications	Withdrawn	
C. General Hospital/General Plastic Surgery			
21	ISO 10555–3: 1996 Sterile, Single-use Intravascular Catheters - Part 3: Central Venous Catheters	Withdrawn duplicate	171
81	ASTM E1061–01(2007) Standard Specification for Direct-Reading Liquid Crystal Forehead Thermometers	Withdrawn and replaced with newer version	200

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
111	IEC 60601–2–38: 1996 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds	Withdrawn duplicate	182
117	ASTM F2172–02:, Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	Contact person	
121	ISO 8536–2–2001 Infusion Equipment for Medical Use - Part 2: Closures for Infusion Bottles	Withdrawn duplicate	173
126	ISO 8536–4:2007 Infusion Equipment for Medical Use -- Part 4: Infusion Sets for Single-use, Gravity Feed	Withdrawn and replaced with newer version	201
162	ISO 8536–1:2000/Amendment 1:2004 Infusion Equipment for Medical Use - Part 1: Infusion Glass Bottles	Withdrawn duplicate	172
D. In Vitro Diagnostics			
31	CLSI H20–A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition	Withdrawn and replaced with newer version	130
E. Materials			
3	ASTM F90–07 Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	Withdrawn and replaced with newer version	145
30	ASTM F1537–07 Standard Specification for Wrought Cobalt–28Chromium–6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Withdrawn and replaced with newer version	152
41	ASTM F2066–07 Standard Specification for Wrought Titanium–15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)	Withdrawn and replaced with newer version	146
42	ASTM F2119–07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	Withdrawn and replaced with newer version	153
45	ASTM F562–07 Standard Specification for Wrought 35Cobalt–35Nickel–20Chromium–10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	Withdrawn and replaced with newer version	147
48	ASTM F899–07 Standard Specification for Stainless Steel for Surgical Instruments	Withdrawn and replaced with newer version	148
56	ISO 5832–1:2007 Implants for Surgery -- Metallic Materials -- Part 1: Wrought Stainless Steel	Withdrawn and replaced with newer version	149
62	ISO 5832–9:2007 Implants for Surgery - Metallic Materials - Part 9: Wrought High Nitrogen Stainless Steel	Withdrawn and replaced with newer version	150
64	ISO 5832–12:2007 Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy	Withdrawn and replaced with newer version	151
F. OB-GYN/Gastroenterology			
5	IEC 60601–2–18 (1996) Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment	Withdrawn duplicate	42
G. Ophthalmic			
35	ISO 10939:2007 Ophthalmic Instruments -- Slit-lamp Microscopes	Contact person	
37	ISO 10942:2006 Ophthalmic Instruments -- Direct ophthalmoscopes	Contact person	
38	ISO 10943:2006 Ophthalmic Instruments -- Indirect ophthalmoscopes	Contact person	
39	ISO 12865:2006 Ophthalmic Instruments -- Retinoscopes	Contact person	
51	ISO 15004–2:2007 Ophthalmic Instruments—Fundamental Requirements and Test Methods Part 2: Light Hazard Protection	Contact person	
H. Radiology			

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
7	IEC / ISO 10918–1:1994 Information Technology--Digital Compression and Coding of Continuous-tone Still Images - Part 1: Requirements and Guidelines	Withdrawn duplicate	150
76	NU 2–2007 Performance Measurements of Positron Emission Tomographs	Withdrawn and replaced with newer version	167
84	IEC 60825–1 Ed. 2.0 (2007) Safety of Laser Products - Part 1: Equipment Classification and Requirements	Withdrawn and replaced with newer version	168
85	IEC 60601–2–22 Ed. 3.0 (2007) Medical Electrical Equipment - Part 2–22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment	Withdrawn and replaced with newer version	169
90	IEC 60601–2–1 (1998–06) Medical Electrical Equipment - Part 2–1: Particular Requirements for the Safety of Electron Accelerators in the Range 1 MeV to 50 MeV	Withdrawn duplicate	152
102	ANSI / IESNA RP–27.2–2000 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - Measurement Techniques	Contact person	
103	ANSI / IESNA RP–27.3–1996 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification and Labeling	Contact person	
112	ISO 11670:2003 Lasers and Laser-related Equipment - Test Methods for Laser Beam Parameters - Beam Positional Stability	Withdrawn duplicate	156
114	ISO 13694:2000 Optics and Optical Instruments - Lasers and Laser-related Equipment - Test Methods for Laser Beam Power (energy) Density Distribution	Withdrawn duplicate	157
119	NEMA PS 3.1 - 3.18 (2007) Digital Imaging and Communications in Medicine (DICOM) Set	Withdrawn and replaced with newer version	170
153	ANSI / IESNA RP–27.1–2005 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - General Requirements	Contact person	
I. Software/Informatics			
4	ANSI/UL 1998 Software in Programmable Components	Relevant guidance	
5	IEC 60601-3-1:1996-08 Medical electrical equipment - Part 3-1: Essential performance requirement for transcutaneous oxygen and carbon dioxide partial pressure monitoring equipment	Relevant guidance	
8	IEC 62304 Ed. 1.0 Medical device software - Software life cycle processes	Relevant guidance	
J. Sterility			
25	ANSI/AAMI/ISO 11135–1:2007 Sterilization of Health Care Products - Ethylene oxide - Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Withdrawn and replaced with newer version	228
63	ASTM F1886: 1998 (2004) Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	Relevant guidance	
64	ASTM F1929:1998 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Relevant guidance	
86	ASTM F1980–07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Withdrawn and replaced with newer version	229
120	ASTM D3078:2002 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Relevant guidance	
136	AAMI/ANSI ST67:2003 Sterilization of Health Care Products - Requirements for Products Labeled 'Sterile' 1st edition	Relevant guidance	
144	ASTM F2203–02(2007) Standard Test Method for Linear Measurement Using Precision Steel Rule	Withdrawn and replaced with newer version	230

TABLE 2.—Continued

Old Item No.	Standard	Change	Replacement Item No.
145	ASTM F2217–02(2007) Standard Practice for Coating/Adhesive Weight Determination	Withdrawn and replaced with newer version	231
146	ASTM F2227–02(2007) Standard Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Medical Packaging Trays by CO_2 Tracer Gas Method	Withdrawn and replaced with newer version	232
147	ASTM F2228–02(2007) Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging Which Incorporates Porous Barrier Material by CO_2 Tracer Gas Method	Withdrawn and replaced with newer version	233
167	ASTM F2097–07 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	Withdrawn and replaced with newer version	234
168	ASTM F2338–05 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	Relevant guidance	
169	ASTM F2391–05 Standard Test Method for Measuring Package and Seal Integrity Using Helium as Tracer Gas	Relevant guidance	
170	ASTM F2475–05 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	Relevant guidance	
193	AAMI/ANSI/ISO 11607–1:2006 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems, 3ed.	Relevant guidance	
194	AAMI/ANSI/ISO 11607–2:2006 Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes, 1ed.	Relevant guidance	
196	ASTM F1140–07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	Withdrawn and replaced with newer version	235
197	ASTM F1608:00(2004) Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	Relevant guidance	
198	ASTM F2054–07 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	Withdrawn and replaced with newer version	236
199	ASTM D4169–05 Standard Practice for Performance Testing of Shipping Containers and Systems	Relevant guidance	
200	ASTM F88–07 Standard Test Method for Seal Strength of Flexible Barrier Materials	Withdrawn and replaced with newer version	237
K. Tissue Engineering			
2	ASTM F2103–01(2007)e1 Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications	Withdrawn and replaced with newer version	12

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: 019.

TABLE 3.

Item No.	Title of Standard	Reference No. & Date
A. Anesthesia		
76	Anaesthetic and Respiratory Equipment—User-applied Labels for Syringes Containing Drugs Used During Anaesthesia—Colours, Design and Performance	ISO 26825:2007
B. Dental/ ENT		

TABLE 3.—Continued

Item No.	Title of Standard	Reference No. & Date
145	Dentistry—Membrane Materials for Guided Tissue Regeneration in Oral and Maxillofacial Surgery—Contents of a Technical File	ISO 22803:2004
146	Dentistry—Metallic Materials for Fixed and Removable Restorations and Appliances	ISO 22674: 2006
C. General Hospital/ General Plastic Surgery		
202	Lasers and Laser-related Equipment -- Test Method and Classification for the Laser-resistance of Surgical Drapes and/or Patient-protective Covers -- Part 2: Secondary Ignition	ISO 11810–2:2007
D. Ophthalmic		
53	Ophthalmic optics—Contact Lenses -- Part 1: Vocabulary, Classification System and Recommendations for Labeling Specifications	ISO 18369–1:2006
54	Ophthalmic Optics- Contact Lenses- Part 4: Physicochemical Properties of Contact Lens Materials	ISO 18369–4:2006
55	Ophthalmic implants -- Intraocular Lenses -- Part 6: Shelf-life and Transport Stability	ISO 11979–6:2007
E. Radiology		
171	Optics and Photonics -- Microlens Arrays -- Part 2: Test Methods for Wavefront Aberrations	ISO 14880–2:2006
172	Optics and Photonics -- Microlens Arrays -- Part 3: Test Methods for Optical Properties Other than Wavefront Aberrations	ISO 14880–3:2006
173	Optics and Photonics -- Microlens Arrays -- Part 4: Test Methods for Geometrical Properties	ISO 14880–4:2006
174	Optics and Photonics -- Lasers and Laser-related Equipment -- Test Methods for Specular Reflectance and Regular Transmittance of Optical Laser Components	ISO 13697:2006
175	Optics and Photonics -- Lasers and Laser-related Equipment -- Measurement of Phase Retardation of Optical Components for Polarized Laser Radiation	ISO 24013:2006
176	Evaluation and Routine Testing in Medical Imaging Departments - Part 3–2: Acceptance Tests - Imaging Performance of Mammographic X-ray Equipment	IEC 61223–3–2 Ed. 2.0 (2007)
F. Sterility		
238	Sterilization of Health Care Products - Chemical Indicators - Part 5: Class 2 Indicators for Bowie and Dick-type Air Removal Tests	ANSI/AAMI/ISO11140–5:2007
239	Aseptic Processing of Health Care Products—Part 3: Lyophilization	ISO 13408–3:2006
240	Aseptic Processing of Health Care Products—Part 5: Sterilization-in-place	ISO 13408–5:2006
241	Aseptic Processing of Health Care Products—Part 6: Isolator Systems	ISO 13408–6:2005
242	Cleanrooms and Associated Controlled Environments—Part 3: Test Methods	ISO 14644–3:2005
243	Cleanrooms and Associated Controlled Environments—Part 6: Vocabulary	ISO 14644–6:2007
244	Cleanrooms and Associated Controlled Environments - Part 8: Classification of Airborne Molecular Contamination	ISO 14644–8:2006

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 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

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: 019'' 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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*.

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: 019. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: December 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24580 Filed 12–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301/496–7057; *fax:* 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Aquaporin 2 Polyclonal Antibodies

Description of Technology: Aquaporins, also known as water channels, form pores in cell membranes and selectively transport water in and out of the cell. Aquaporins are involved in regulation of water balance and blood pressure, and thirteen different isoforms have been found in mammals. Aquaporin 2 (AQP2) is located in the collecting duct of the kidney, and is regulated by the peptide hormone vasopressin. AQP2 expression is increased in conditions where there is water retention, such as pregnancy and congestive heart failure, and mutations of AQP2 are associated with nephrogenic diabetes insipidus. Also, lithium treatment, often administered for bipolar disorder, can cause acquired diabetes insipidus by decreasing AQP2 expression.

The inventors have developed rabbit polyclonal antibodies directed against a peptide sequence in the C-terminal region of AQP2 (LKGLEPDTDWEEREVRRRQ). The sequence is upstream of phosphorylation sites in this region, and consequently the antibodies recognize both unphosphorylated and phosphorylated AQP2. The sequence is identical in human, rat, mouse, cow, and sheep.

Applications: Western blotting, immunohistochemistry, and immunoprecipitation.

Inventor: Mark A. Knepper (NHLBI).

Related Publication: SR DiGiovanni, S Nielsen, EI Christensen, MA Knepper. Regulation of collecting duct water channel expression by vasopressin in Brattleboro rat. Proc Natl Acad Sci U S A. 1994 Sep 13;91(19):8984–8988.

Patent Status: HHS Reference No. E–045–2008/0—Research Tool. Patent prosecution is not being pursued for this technology.

Licensing Status: This technology is available as a research tool under a Biological Materials License.

Licensing Contact: Tara L. Kirby, PhD; 301/435–4426; *tarak@mail.nih.gov*.

Treatment for Chronic Inflammatory Disease and Cancer by Inhibition of MMP–1

Description of Technology: The breakdown of connective tissue is a feature of many pathological diseases, including tumors as well as inflammatory diseases such as atherosclerosis, rheumatoid arthritis, and periodontitis. Proteases involved in connective tissue turnover, such as matrix metalloproteinases (MMPs) and the plasminogen activation system, have been shown to play a pivotal role in inflammatory disease and in tumor cell invasion, growth and metastasis. Matrix metalloproteinase-1 (MMP–1), a collagenase, is expressed in areas of rapid remodeling of the extracellular matrix in both normal and pathological conditions.

The inventors have determined that the serine protease plasmin stimulates MMP–1 production in monocytes through binding to the annexin A2 heterotetramer. The inventors have also determined that inactive plasmin is an inhibitor of plasmin induction of MMP–1. The invention discloses new methods of suppressing inflammation and tumors through inhibition of plasmin activity, for example by using agents, including inactive plasmin, to inhibit plasmin-stimulated MMP–1 production.

Applications: Therapeutics for inflammatory disease and tumor suppression.

Market: In the United States, approximately two percent of the population have atherosclerosis, more than five percent have an autoimmune inflammatory disease, and approximately fifty percent of all adults over thirty have periodontitis.

Development Status: Early stage.

Inventors: Yahong Zhang and Larry M. Wahl (NIDCR).