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


Randall W. Lutter,
Associate Commissioner for Policy and Planning.

[FR Doc. E7–9737 Filed 5–18–07; 8:45 am]

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: 017

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 standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 017” (Recognition List Number: 017), will assist manufacturers who elect to declare conformity with standards not previously recognized by FDA.

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

ADDRESSES: Submit written requests for single copies of “Modifications to the List of Recognized Standards, Recognition List Number: 017” 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: 017 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, 2000 Gaither Road, Rockville, MD 20850, 240–276–0533.

I. Background


In a notice published in the Federal Register of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled “Guidance on the Recognition and Use of Consensus Standards.” The notice described how FDA would implement its standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 017

FDA is announcing 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.

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.

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.

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<td>63 FR 55617</td>
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<td>192</td>
<td>ASTM F1223–05: Standard Test Method for Determination of Total Knee Replacement Constraint</td>
<td>Contact Person</td>
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<tr>
<td>J. Radiology</td>
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<td>101</td>
<td>ANSI / IESNA RP–27.1–05 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements</td>
<td>Withdrawn and replaced with newer version</td>
<td>153</td>
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<td>104</td>
<td>IEC 60601–2–33 (2006), Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis</td>
<td>Withdrawn and replaced with newer version</td>
<td>161</td>
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<tr>
<td>K. Software</td>
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<td>6</td>
<td>IEEE 1012–2004 Standard for Software Verification and Validation</td>
<td>Withdrawn</td>
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<td>7</td>
<td>AAMI / ANSI SW68:2001 Medical Device Software—Software Life Cycle Processes</td>
<td>Withdrawn</td>
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<td>L. Sterility</td>
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<tr>
<td>121</td>
<td>ASTM D4169–05, Standard Practice for Performance Testing of Shipping Containers and Systems</td>
<td>Withdrawn and replaced with newer version</td>
<td>199</td>
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### TABLE 2.—Continued

<table>
<thead>
<tr>
<th>Old Item No.</th>
<th>Standard</th>
<th>Change</th>
<th>Replacement Item No.</th>
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<tr>
<td>M. Tissue Engineering</td>
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</table>

### 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: 017.

### TABLE 3.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Title of Standard</th>
<th>Reference No. &amp; Date</th>
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</thead>
<tbody>
<tr>
<td>A. Anesthesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Cardiovascular/Neurology</td>
<td></td>
<td></td>
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<tr>
<td>C. Dental/ENT</td>
<td></td>
<td></td>
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<tr>
<td>141</td>
<td>Dental Base Metal Casting Alloys—Part 1: Cobalt-based Alloys</td>
<td>ISO 6871–1:1994</td>
</tr>
<tr>
<td>D. General</td>
<td></td>
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<tr>
<td>E. General Hospital/General Plastic Surgery</td>
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<tr>
<td>176</td>
<td>Standard Guide for Assessment of Medical Gloves</td>
<td>ASTM D7103–06</td>
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<tr>
<td>179</td>
<td>Needle-free Injectors for Medical Use—Requirements and Test Methods</td>
<td>ISO 21649:2006</td>
</tr>
<tr>
<td>F. In Vitro Diagnostic</td>
<td></td>
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<tr>
<td>129</td>
<td>Quality Control of Microbiological Transport Systems</td>
<td>CLSI M40–A 2003</td>
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<tr>
<td>G. Materials</td>
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<td></td>
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<tr>
<td>135</td>
<td>Standard Test Method for Burst Strength of Surgical Sealants</td>
<td>ASTM F2392–04</td>
</tr>
<tr>
<td>136</td>
<td>Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants</td>
<td>ASTM F2458–05</td>
</tr>
</tbody>
</table>
### 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](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 “Modifications to the List of Recognized Standards, Recognition List Number: 017” will be available on the CDRH home page. You may access the CDRH home page at [http://www.fda.gov/cdrh](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](http://www.fda.gov/cdrh/STDSProg.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

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Title of Standard</th>
<th>Reference No. &amp; Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. OB-GYN/Gastroenterology</td>
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<tr>
<td>43</td>
<td>Rubber Condoms—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms</td>
<td>ISO 16038:2005</td>
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<tr>
<td>I. Ophthalmic</td>
<td></td>
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<tr>
<td>J. Radiology</td>
<td></td>
<td></td>
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<tr>
<td>158</td>
<td>Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging</td>
<td>NEMA MS 10–2006</td>
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<tr>
<td>159</td>
<td>Determination of Gradient-Induced Electric Fields In Diagnostic Magnetic Resonance Imaging</td>
<td>NEMA MS 11–2006</td>
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<tr>
<td>160</td>
<td>Quantification and Mapping of Geometric Distortion for Special Applications</td>
<td>NEMA MS 12–2006</td>
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### TABLE 3.—Continued

<table>
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<tr>
<th>Item No.</th>
<th>Title of Standard</th>
<th>Reference No. &amp; Date</th>
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</thead>
</table>
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: 017. These modifications to the list or recognized standards are effective upon publication of this notice in the Federal Register.

Linda S. Kahan,
Deputy Director, Center for Devices and Radiological Health.

BILLING CODE 4160

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.

ADDRESS: 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.

A Method With Increased Yield for Production of Polysaccharide-Protein Conjugate Vaccines Using Hydrazide Chemistry

Description of Technology: Current methods for synthesis and manufacturing of polysaccharide-protein conjugate vaccines employ conjugation reactions with low efficiency (about twenty percent). This means that up to eighty percent of the added activated polysaccharide (PS) is lost. In addition, inclusion of a chromatographic process for purification of the conjugates from unconjugated PS is required.

The present invention utilizes the characteristic chemical property of hydrazide groups on one reactant to react with aldehyde groups or cyanate esters on the other reactant with an improved conjugate yield of at least sixty percent. With this conjugation efficiency the leftover unconjugated protein and polysaccharide would not need to be removed and thus the purification process of the conjugate product can be limited to diafiltration to remove the by-products of small molecules. The new conjugation reaction can be carried out within one or two days with reactant concentrations between 1 and 25 mg/mL at PS/protein ratios from 1:2 to 3:1, at temperatures between 4 and 40 degrees Centigrade, and in a pH range of 5.5 to 7.4, optimal conditions varying from PS to PS.

Application: Cost effective and efficient manufacturing of conjugate vaccines.

Inventors: Che-Hung Robert Lee and Carl E. Frasch (CBER/FDA).


Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukas@mail.nih.gov.

A Method for Immunizing Humans Against Salmonella Typhi Using a Vi-EEPA Conjugate Vaccine

Description of Technology: This invention is a method of immunization against typhoid fever using a conjugate vaccine comprising the capsular polysaccharide of Salmonella typhi, Vi, conjugated through an adipic dihydrazide linker to nontoxic recombinant exo-protein A (rEPA) from Pseudomonas aeruginosa. The three licensed vaccines against typhoid fever, attenuated S. typhi Ty21a, killed whole cell vaccines and Vi polysaccharide, have limited efficacy, in particular for children under 5 years of age, which make an improved vaccine desirable.

It is generally recognized that an effective vaccine against Salmonella typhi is one that increases serum anti-Vi IgG eight-fold six weeks after immunization. The conjugate vaccine of the invention increases anti-Vi IgG, 48-fold, 252-fold and 400-fold in adults, in 5–14 years-old and 2–4 years-old children, respectively. Thus this is a highly effective vaccine suitable for children and should find utility in endemic regions and as a traveler’s vaccine. The route of administration can also be combined with routine immunization. In 2–5 years old, the protection against typhoid fever is 90% for 4 years. In school age children and in adults the protection could mount to complete protection according to the immunogenicity data.

Application: Immunization against Salmonella typhi for long term prevention of typhoid fever in all ages.

Development Status: Conjugates have been synthesized and clinical studies have been performed. The synthesis of the conjugates is described by Kossaczka et al. in Infect Immun. 1997 June;65(7):2088–2093. Phase III clinical studies are described by Mai et al. in N Engl J Med. 2003 October 2; 349(14):1390–1391. Dosage studies are described by Ganh et al. in Infect Immun. 2004 Nov;72(11):6586–6588.

A safety and immunogenicity study in infants are underway. The aim is to administer the conjugate vaccine with routine infant immunization. Preliminary results show the vaccine is safe in 2 months old infants.

Inventors: Zuzana Kossaczka, Shousun C. Szu, and John B. Robbins (NICHD).


Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301/435–4646; soukas@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Laboratory of Developmental and Molecular Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A Method of Immunizing Humans Against Salmonella Typhi Using a Vi-EEPA Conjugate Vaccine. Please contact John D. Hewes, Ph.D., at 301–435–3121 or hewesj@mail.nih.gov for more information.