FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 005

FDA is announcing the addition, withdrawal, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews 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: 005” to identify: (1) Supplementary information sheets for standards added to the list for the first time, (2) standards added to replace withdrawn standards, and (3) still recognized standards for which minor revisions are made to clarify the application of the standards.

At the end of this notice, FDA lists modifications the agency is making that involve: (1) The initial addition of standards not previously recognized by FDA and (2) the addition of standards in conjunction with the withdrawal of other standards that are replaced by these later, amended, or different standards.

In this section, FDA describes modifications that involve the withdrawal of standards and their replacement by others. In this notice, all changes of this type are in the sterility category of the complete list of recognized standards.

1. ASTM-F1140:1996 is withdrawn under previous item 59. ASTM-F1140:2000 is added under current item 67.
2. ASTM-F1585:1995 is withdrawn under previous item 61. ASTM F1585:2000 is added under current item 68.

III. 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 Intranet site at http://
V. 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 800–899–0361 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.

Persons interested in obtaining a copy of “Guidance on the Recognition and Use of Consensus Standards” may also do so by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes this 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: 005” will be available on the CDRH home page. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The “Guidance on the Recognition and Use of Consensus Standards,” and the searchable database for “FDA Recognized Consensus Standards,” may be accessed through hyper links at http://www.fda.gov/cdrh/standards.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.

VI. Submission of Comments and Effective Date

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be considered in determining whether to amend the current listing of “Modifications to the List of Recognized Standards, Recognition List Number: 005.”

The recognition of standards announced in this notice of modifications will become effective on May 7, 2001.

VII. 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: 005, is as follows:

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Title of Standards</th>
<th>Reference Number and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anesthesia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cardiovascular/Neurology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Applications</td>
<td>ASTM F647–94</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Standard for the Development of an Electrostatic Discharge Control Program</td>
<td>ANSI/ESD S20.20–1999</td>
</tr>
<tr>
<td>26</td>
<td>Medical Devices–Application of Risk Management to Medical Devices</td>
<td>ISO 14971:2000</td>
</tr>
<tr>
<td><strong>Sterility</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

David W. Feigal, Jr.,
Director, Center for Devices and Radiological Health.

[FR Doc. 01-11329 Filed 5-4-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Application for the Pharmacology Research Associate Program

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on February 6, 2001, pages 9089–9090, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Application for the Pharmacology Research Associate Program. Type of Information Collection Request: Extension of a currently approved collection. Need and Use of Information Collection: The Pharmacology Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a PhD, degree in pharmacology or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of Health or the Food and Drug Administration. The goal of the program is to develop leaders in pharmacological research for key positions in academic, industrial, and Federal research laboratories. Frequency of Response: Once a year. Affected Public: Individuals or households; Businesses or other for-profit.

The annual reporting burden is as follows:

<table>
<thead>
<tr>
<th>Type and numbers of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Estimated total responses</th>
<th>Average burden hours per responses</th>
<th>Estimated total annual burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicants—50</td>
<td>1</td>
<td>50</td>
<td>2.00</td>
<td>100</td>
</tr>
<tr>
<td>Referees—150</td>
<td>1</td>
<td>150</td>
<td>0.167</td>
<td>25</td>
</tr>
</tbody>
</table>

Total Number of Respondents: 200
Total Number of Responses: 200
Total Hours: 125
The annualized cost to respondents is estimated at:
Applicants: $5,500.00
Referees: $1,250.00
There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments:

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503. Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Sally Lee, NIGMS, NIH, Natcher Building, Room 2AN–18H, 45 Center Drive, MSC 6200, Bethesda, MD 20892–6200. Phone (301) 594–2755, facsimile (301) 402–0156, or electronic mail: LeeS@nigms.nih.gov.

Comments Due Date:

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.


Martha Pine,
Associated Director for Administration and Operations, National Institute of General Medical Sciences.

[FR Doc. 01-11329 Filed 5-4-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Case-Cohort Study of Cancer and Related Disorders Among Benzene-Exposed Workers in China

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on December 28, 2000, pages 82382–82383 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Case-Cohort (formerly Case-Control) Study of Cancer and Related Disorders Among