review in 2002 by the IOM's Immunization Safety Review Committee. This will be the first opportunity for the public to provide comments on the hypotheses that are being considered for future review.

Agenda items are subject to change as priorities dictate. A complete meeting agenda of the Subcommittee on VaccineSafety and Communications can be found on the NationalVaccine Program Office's web site at *www.cdc.gov/od/nvpo/calendar.*

CONTACT PERSON FOR MORE INFORMATION: Ms. Shaunette Crawford, Associate Director for Health Communications and Legislation, NVPO, CDC, 1600 Clifton Road, NE, M/S D–66, Atlanta, Georgia 30333, telephone 404/687–6672.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 1, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–11371 Filed 5–4–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

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

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 will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 005'' (Recognition List Number: 005) will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written comments concerning this document at any time. See section VI 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: 005,'' 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 to the contact person (address below). Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed on FDA's Internet site at http://www.fda.gov/cdrh/fedregin.html. See section V of this document for electronic access to the searchable database for the current list of ''FDA Recognized Consensus Standards,'' including Recognition List Number: 005 modifications, and other standards related information.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: 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 the guidance entitled ''Recognition and Use of Consensus Standards.'' This notice described how FDA will implement its standards program recognizing the use of certain standards 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), and November 15, 2000 (65 FR 69022), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. When these notices were published, the agency maintained ''html'' and ''pdf'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions were publicly accessible at the agency's Internet site. The agency maintains the current list in a searchable database accessible to the public. See section V of this document for electronic access information.

II. Discussion of Modifications to the List of Recognized Standards, Recognition List Number: 005

FDA is announcing the addition, withdrawal, correction, 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.

3. ASTM–1608:1995 is withdrawn under previous item 62. ASTM F1608:2000 is added under current item 69.

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://

www.acessdata.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.

IV. 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 (address above). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of standards, (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.

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 800–899–0381 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.

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/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.

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:

Item Number	Title of Standards	Reference Number and Date
	Anesthesia	
34	Standard Test Method for Evaluation the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	ASTM PS127:2000
	Cardiovascular/Neurology	
31	Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Applications	ASTM F647–94
32	Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips	ASTM F1542–94 (2000)
33	Neurosurgical Implants–Sterile, Single-Use Hydrocephalus Shunts and Components	ISO 7197:1997
	General	
25	Standard for the Development of an Electrostatic Discharge Control Program	ANSI/ESD S20.20–1999
26	Medical Devices–Application of Risk Management to Medical Devices	ISO 14971:2000
	Sterility	
67	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications	ASTM F1140:2000
68	Standard Guide for Integrity Testing of Porous Barrier Medical Packages	ASTM F1585:2000
69	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	ASTM F1608:2000

Dated: April 24, 2001.

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:

Type and numbers of respondents	Estimated number of responses per respondent	Estimated total responses	Average burden hours per responses	Estimated total annual burden hours requested
Applicants—50	1	50	2.00	100
Referees—150	1	150	0.167	25

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.

Dated: April 30, 2001.

Martha Pine,

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

[FR Doc. 01–11392 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