TABLE 3—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference Number and date</th>
</tr>
</thead>
</table>

¹ All standard titles in this table conform to the style requirements of the respective organizations.

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 once a year, or more often, if necessary, in the Federal Register.

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 FD&C 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: 028” will be available on the CDRH home page. You may access the CDRH home page at http://www.fda.gov/MedicalDevices.


This Federal Register document on modifications in FDA’s recognition of consensus standards is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see FOR FURTHER INFORMATION CONTACT) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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: 028. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: March 12, 2012.

Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2012–6389 Filed 3–15–12; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency’s Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries of safety and effectiveness.
II. Electronic Access

Persons with access to the Internet may obtain the documents at:
http://www.fda.gov/MedicalDevices/
ProductsandMedicalProcedures/
DeviceApprovalsandClearances/
PMAApprovals/default.htm; and
http://www.fda.gov/MedicalDevices/
ProductsandMedicalProcedures/
DeviceApprovalsandClearances/
HDEApprovals/ucm161827.htm.

Dated: March 12, 2012.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Child Health Disparities Measurement for the National Children’s Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the