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

Recognition No.	Title of standard [1]	Reference Number and date
	M. Tissue Engineering	
15–32	Standard Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy.	ASTM F2260–03 (Reapproved 2008).
15–33	Standard Test Method for Determining the Molar Mass of Chitosan and Chitosan Salts by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	ASTM F2602–08 [1].
15–34	Standard Test Method for Determining the Molar Mass of Sodium Alginate by Size Exclusion Chromatography with Multi-angle Light Scattering Detection (SEC–MALS).	ASTM F2605–08 [1].
15–35	Standard Guide for Characterization of Hydrogels used in Regenerative Medicine	ASTM F2900–11.
15–36	Standard Guide for Assessment of Adventitious Agents in Tissue Engineered Medical Products (TEMPs).	ASTM F2383–11.

[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 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 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.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

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 or 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

[Docket Nos. FDA–2011–M–0735, FDA–2011–M–0736, FDA–2011–M–0737, FDA–2011–M–0746, FDA–2011–M–0786, FDA–2011–M–0791, FDA–2011–M–0792, FDA–2011–M–0796, FDA–2011–M–0832, FDA–2011–M–0837, FDA–2011–M–0848, FDA–2011–M–0865, FDA–2011–M–0866, FDA–2011–M–0910, and FDA–2011–M–0917]

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.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2011, through December 31, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2011, THROUGH DECEMBER 31, 2011

PMA No., Docket No.	Applicant	Trade name	Approval date
P110003, FDA–2011–M–0746	Pluromed, Inc	LEGOO	September 28, 2011.
P090024, FDA–2011–M–0737	Siemens Healthcare Diagnostics	ADVIA CENTAUR HBEAG assay and quality control material.	October 11, 2011.
P040024 (S51), FDA–2011–M–0735	Medicis Aesthetics, Inc	RESTYLANE injectable gel	October 11, 2011.
P010029 (S8), FDA–2011–M–0736	Ferring Pharmaceuticals, Inc	EUFLEXXA (1% sodium hyaluronate)	October 11, 2011.
P110022, FDA–2011–M–0786	Roche Diagnostics Corp	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM.	October 26, 2011.
P110011, FDA–2011–M–0791	Medtronic Ireland	ASSURANT COBALT iliac balloon-expandable stent system.	October 26, 2011.
P100042, FDA–2011–M–0792	Gen-Probe Incorporated	APTIMA HPV assay	October 28, 2011.
P110019, FDA–2011–M–0796	Abbott Vascular	XIENCE PRIME and XIENCE PRIME LL EVEROLIMUS-eluting coronary stent system.	November 1, 2011.
P100041, FDA–2011–M–0837	Edwards Lifesciences, LLC	EDWARDS SAPIEN transcatheter heart valve and RETROFLEX 3 delivery system, RETROFLEX balloon catheter and crimper.	November 2, 2011.
P090016, FDA–2011–M–0832	Merz Aesthetics, Inc	BELOTERO balance	November 14, 2011.
H090002, FDA–2011–M–0848	BSD Medical Corp	BSD–2000 hyperthermia system	November 18, 2011.
P110010, FDA–2011–M–0865	Boston Scientific Corp	PROMUS ELEMENT PLUS EVEROLIMUS-eluting platinum chromium coronary stent system.	November 22, 2011.
P100024, FDA–2011–M–0866	Dako Denmark A/S	*HER2* CISH PHARMDX kit	November 30, 2011.
P110025, FDA–2011–M–0917	Roche Diagnostics Corp	ELECSYS anti-HBC IGM immunoassay and ELECSYS PRECICONTROL anti-HBC IGM for use on the MODULAR ANALYTICS E170 immunoassay analyze.	December 14, 2011.
P100046, FDA–2011–M–0910	AtriCure Inc	ATRICURE SYNERGY ablation system.	December 14, 2011.

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.

[FR Doc. 2012–6390 Filed 3–15–12; 8:45 am]

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