no standards or regulatory requirements that specifically address scoring of tablets, the Agency recognizes the need for consistent scoring between a generic product and its RLD.

Consistent scoring ensures that the patient is able to adjust the dose, by splitting the tablet, in the same manner as the RLD. This enables the patient to switch between products made by different manufacturers without encountering problems related to the dose. In addition, consistent scoring ensures that neither the generic product nor the RLD has an advantage in the marketplace because one is scored and one is not.

The Center for Drug Evaluation and Research's Drug Safety Oversight Board considered the practice of tablet splitting at its October 2009 and November 2010 meetings. During those meetings, they discussed how insurance companies and doctors are increasingly recommending that patients split tablets, either to adjust the patients' dose or as a cost-saving measure. Because of this, the Agency conducted internal research on tablet splitting and concluded that in some cases, there are possible safety issues, especially when tablets are not scored or evaluated for splitting. The Agency's concerns with splitting a tablet included variations in the tablet content, weight, disintegration, or dissolution, which can affect how much drug is present in a split tablet and available for absorption. In addition, there may be stability issues with splitting tablets.

Tablet splitting also is addressed in pharmacopeial standards. The European Pharmacopeia currently applies accuracy of subdivision standards for scored tablets—and has at various times also included standards for content uniformity, weight variation, and loss of mass—while the United States Pharmacopeia published a Stimuli article in 2009 proposing criteria for loss of mass and accuracy of subdivision for split tablets.

As an outgrowth of these discussions, FDA is providing recommendations for application content regarding the scientific basis for functional scoring on solid oral dosage form products to ensure the quality of both NDA and ANDA scored tablet products. To accomplish this, the Agency has developed consistent and meaningful criteria by which scored tablets can be evaluated and labeled by: (1) Providing a harmonized approach to chemistry, manufacturing, and controls reviews of scored tablets; (2) ensuring consistency in nomenclature (e.g., score versus bisect) and labeling; and (3) providing information through product labeling or other means to health care providers.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on tablet scoring: Nomenclature, labeling, and data for evaluation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 201.57 (21 CFR 201.57) and 21 CFR 314.50 and 314.70 have been approved under OMB control numbers 0910–0572 (for § 201.57) and 0910–0001 (for 21 CFR part 314).

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05725 Filed 3–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/Xavier University Global Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University Global Medical Device Conference.'' This 3-day public conference includes presentations from key FDA officials and industry experts with small group breakout sessions. The conference is intended for companies of all sizes and employees at all levels.

Date and Time: The public conference will be held on May 1, 2013, from 8:30 a.m. to 5 p.m.; May 2, 2013, from 8:30 a.m. to 5 p.m.; and May 3, 2013, from 8:30 a.m. to 1 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073 or 513–745–3396.

Contact Persons: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, Fax: 513–679–2771, *Gina.Brackett@fda.hhs.gov.*

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3073, *phillipsm4@xavier.edu.*

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the conference. Early registration ends March 13, 2013. Standard registration ends April 9, 2013. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Advanced rate (March 13, 2013 to April 8, 2013)	Standard rate (April 9, 2013 to May 3, 2013)
Industry	$1,295	$1,495
Small Business (<100 employees)	900	1,000
Consultant	600	700
Startup Manufacturer	250	300
Academic	250	300
FDA/Government Employee	(2)	Free

[1] The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.
[2] Free.

To register online for the public conference, please visit the ''Register Now'' link on the conference Web site at *http://www.XavierMedCon.com.* FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth St., Cincinnati, OH, 45202, 513–421–9100. Special Conference Block rates are available through April 9, 2013. To make reservations online, please visit the ''Venue & Logistics'' link at *http://www.XavierMedCon.com.*

If you need special accommodations due to a disability, please contact Marla Phillips (see Contact Persons) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- CDRH Future Vision and Strategy Keynote Address
- U.S. Congressman Erik Paulsen Keynote Dinner
- EU Regulations: New Regulations, Company Strategy, and Open Discussion Forum
- FDA Safety and Innovation Act
- Unique Device Identification
- Update from the Office of Device Evaluation
- Total Product Life Cycle: Interactive Workshop
- Pre-Submission Program and Meetings with the FDA
- 510(k): New FDA Guidance and Industry Regulations
- PMAs: New Guidance and Compliance Initiatives
- Software and Mobile Apps
- Combination Products
- Entering the EU Market and CE Mark Hot Topics
- Global Product Strategy
- Success in Central and South America
- FDA Inspectional Approach—Panel with Current FDA Investigators

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: March 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05727 Filed 3–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Pediatric Palliative Care Campaign Pilot Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Nursing Research (NINR), 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 26, 2012, page 76053 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 Institute of Nursing Research (NINR), 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.

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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment 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.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Adrienne Burroughs, Health Communications Specialist, Office of Communications and Public Liaison, NINR, NIH, Building 31, Room 5B10, 31 Center Drive, Bethesda, MD 20892 or call non-toll-free number (301) 496–0256 or Email your request, including your address to: *adrienne.burroughs@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Pediatric Palliative Care Campaign Pilot Survey,