sponsor may disagree with one of these decisions, and a dispute arises. Because these disputes often involve complex scientific or procedural matters and also may be precedent setting, it is critical that there be procedures in place to encourage open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and procedural disputes between sponsors and FDA. This draft guidance is a revision of the guidance of the same name that published in February 2000. The procedures and policies have been updated to reflect the current practices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on formal dispute resolution regarding appeals above the division level. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 The collections of information in this draft guidance have been approved under OMB control number 0910–0430. This draft guidance is a revision of an earlier version of the guidance. The revised version contains no additional information collections; therefore, it continues to be covered under OMB control number 0910–0430.

III. 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.*

IV. Electronic Access

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

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05721 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–2011–D–0595]

Guidance for Industry on Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.'' This guidance provides recommendations to sponsors of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding what criteria should be met when evaluating and labeling tablets that have been scored. (A scoring feature facilitates tablet splitting, which is the practice of breaking or cutting a higher-strength tablet into smaller portions.) Specifically, this guidance recommends guidelines to follow, data to provide, and criteria to meet and detail in an application to support approval of a scored tablet; and nomenclature and labeling for approved scored tablets.

This guidance does not address specific finished-product release testing, where additional requirements may apply to scored tablets. This guidance does not describe the medical practice conditions under which tablet splitting is considered or recommended.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Russell Wesdyk, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4182, Silver Spring, MD 20993–0002, 301–796–2400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.'' This guidance provides recommendations to sponsors of NDAs and ANDAs regarding what criteria should be met when evaluating and labeling tablets that have been scored. (A scoring feature facilitates tablet splitting, which is the practice of breaking or cutting a higher-strength tablet into smaller portions.) Specifically, this guidance recommends:

- Guidelines to follow, data to provide, and criteria to meet and detail in an application to support approval of a scored tablet; and
- Nomenclature and labeling for approved scored tablets.

On August 30, 2011 (76 FR 53909), FDA announced the availability of the draft version of this guidance. The public comment period closed on November 28, 2011. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. The Agency also held an Advisory Committee for Pharmaceutical Science and Clinical Pharmacology meeting on August 9, 2012, to discuss the draft guidance. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

The Agency has previously considered tablet scoring as an issue when determining whether a generic drug product is the same as the reference listed drug (RLD). One characteristic of a tablet dosage form is that it may be manufactured with a score or scores. This characteristic is useful because the score can be used to facilitate the splitting of the tablet into fractions when less than a full tablet is desired for a dose. Although there are

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: