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 This draft guidance is a revision of the guidance of the same name that published in February 2000.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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on formal dispute resolution regarding appeals above the division level.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This draft guidance refers to previously approved collections of information found in FDA regulations.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 The collections of information in this draft guidance have been approved under OMB control number 0910–0430. This draft guidance is a revision of an earlier version of the guidance.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


Dated: March 7, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013–05721 Filed 3–12–13; 8:45 am]

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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.

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
biset) 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
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III. The Paperwork Reduction Act of
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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
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/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm or http://
www.regulations.gov.

Dated: March 7, 2013.

Leslie Kux,
Assistant Commissioner for Policy.