

mg, were not discontinued from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. In addition, we have considered that the 7.5 mg and 15 mg strengths are bracketed by other strengths that are still being marketed. We have found no information that would indicate that OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of ANDAs that refer to these drug products. Additional ANDAs that refer to OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0595]

#### Draft Guidance for Industry on Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation; Availability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 draft guidance for industry entitled "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation." This draft guidance provides recommendations to sponsors of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding what criteria should be met to facilitate the evaluation and labeling of 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 draft guidance recommends guidelines to follow, data to provide, and criteria to meet and detail in an application to approve 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 be appropriate for scored tablets.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 28, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft 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 draft guidance document.

Submit electronic comments on the draft 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, 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 draft guidance for industry entitled "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation." This draft guidance provides recommendations to sponsors of NDAs and ANDAs regarding what criteria should be met to facilitate the evaluation and labeling of 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 draft guidance recommends:

- Guidelines to follow, data to provide, and criteria to meet and detail in an application to approve a scored tablet.

- Nomenclature and labeling for approved scored tablets.

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.

CDER'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.<sup>1</sup>

As an outgrowth of these discussions and developments, FDA is providing recommendations for application content regarding the scientific basis for functional scores 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. The criteria are as follows: (1) Provide a harmonized approach to chemistry, manufacturing, and controls reviews of scored tablets; (2) ensure consistency in nomenclature (e.g., score versus bisect) and labeling; and (3) provide information through product labeling or other means to healthcare providers.

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 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of

comments. It is no longer necessary to send two copies of mailed 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.

## III. 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 21 CFR 201.57, 314.50, and 314.70 have been approved under OMB control numbers 0910–0572 (for section 201.57) and 0910–0001 (for 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: August 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0594]

### Fee for Using a Priority Review Voucher in Fiscal Year 2012

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2012. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for approval of drug or biological products when those applications use a priority review voucher awarded by the Secretary of Health and Human Services. These vouchers are awarded to the sponsors of certain tropical disease

product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee to be submitted to FDA with applications using a priority review voucher is determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY. This notice establishes the priority review fee rate for FY 2012.

**FOR FURTHER INFORMATION CONTACT:** David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Picard Dr., Rockville, MD 20850, 301–796–7103.

## SUPPLEMENTARY INFORMATION:

### I. Background

Section 1102 (under title XI) of FDAAA (Pub. L. 110–85) added new section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of certain tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a qualified tropical disease (as defined in section 524(a)(3)), shall receive a priority review voucher upon approval of the tropical disease product application. The recipient of a priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (21 U.S.C. 262), or transfer (including by sale) the voucher to another party that may then use it. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months.

The applicant that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA has published a draft guidance on its Web site about how this priority review voucher program will operate (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf>).

This notice establishes the priority review fee rate for FY 2012 of \$5,280,000 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2011, and will remain in effect through September 30, 2012, for applications submitted with a priority review voucher. The payment of

<sup>1</sup> Geoff Green et al., November–December 2009, 35(6), “Pharmacopeial Standards for the Subdivision Characteristics of Scored Tablets,” *Pharmacopeial Forum*.