''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 7, 2011 (Docket No. FDA–2011–P–0460), under 21 CFR 10.30, requesting that the Agency determine whether TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, have been voluntarily withdrawn or withheld from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, 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. ANDAs that refer to TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, 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.

[FR Doc. 2011–22145 Filed 8–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–P–0182 and FDA–2011–P–0209]

Determination That OPANA ER (Oxymorphone Hydrochloride) Extended-Release Tablets, 7.5 Milligrams and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that OPANA ER (oxymorphone hydrochloride (HCl)) extended-release tablets, 7.5 milligrams (mg) and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs for oxymorphone HCl extended-release tablets, 7.5 mg and 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under §§ 10.25(a) and 10.30 (21 CFR 10.25(a) and 10.30). Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, are the subject of NDA 021610, held by Endo Pharmaceuticals, and initially approved on June 22, 2006. OPANA ER is indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. There are approved ANDAs for oxymorphone HCl extended-release tablets, 7.5 mg and 15 mg; these ANDAs are listed in the Orange Book. The other strengths of OPANA ER—both lower and higher strengths than 7.5 mg and 15 mg—continue to be marketed.

Watson Laboratories, Inc., submitted a citizen petition dated March 21, 2011 (Docket No. FDA–2011–P–0182), under § 10.30, requesting that the Agency determine whether OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness. In addition, K&L Gates submitted a citizen petition dated March 25, 2011 (Docket No. FDA–2011–P–0209), under § 10.30, requesting that the Agency determine that OPANA ER (oxymorphone HCl) extended-release tablets, 7.5 mg and 15

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.

[FR Doc. 2011–22143 Filed 8–29–11; 8:45 am]

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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.