include all applicable State procedures, designations, and certifications for each requirement as well as supporting documentation. A State may use a pre-print format prepared by the Office of Refugee Resettlement (ORR) of the Administration for Children and Families (ACF) or a different format, on the condition that the format used meets all of the State plan requirements under Title IV of the Act and ORR regulations at 45 CFR part 400.

There is no schedule for submission of this State Plan, as all States are currently operating under an approved plan and are in compliance with regulations at 45 CFR 400.4 400.9. Per 45 CFR 400.4(b), States need only certify that the approved plan is current and continues in effect, no later than 30 days after the beginning of the Federal fiscal year. Consistent with regulations, if States wish to revise or amend the plan, a revised plan or plan amendment must be submitted to ORR as described at 45 CFR 400.7 400.9.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV State Plan	50	1	15	750

Estimated Total Annual Burden Hours: 750.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–22078 Filed 8–29–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0460]

Determination That TALWIN COMPOUND (Aspirin; Pentazocine Hydrochloride) Tablets, 325 Milligrams; Equivalent to 12.5 Milligram Base, 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 TALWIN COMPOUND (aspirin; pentazocine hydrochloride (HCl)) tablets, 325 milligrams (mg); equivalent to (EQ) 12.5 mg base, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for aspirin; pentazocine HCl tablets, 325 mg; EQ 12.5 mg base, 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, are the subject of NDA 016891, held by Sanofi-aventis U.S., and initially approved on November 12, 1975. TALWIN COMPOUND tablets are indicated for the relief of moderate pain.

TALWIN COMPOUND (aspirin; pentazocine HCl) tablets, 325 mg; EQ 12.5 mg base, are currently listed in the

''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]

BILLING CODE 4160–01–P

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