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:

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**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COMPOUND (Aspirin; Pentazocine Hydrochloride) Tablets, 325 Milligrams; Equivalent to 12.5 Milligram Base, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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(aspirin; pentazocine hydrochloride (HCl)) tablets, 325 milligrams (mg); equivalent to (EQ) 12.5 mg base, were not withdrawn from sale for reasons of safety or effectiveness.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 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 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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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

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