Dated: March 31, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–8654 Filed 4–11–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Plan for Child Support under IV–D of the Social Security Act.

OMB No.: 0970–0017.

Description: The Office of Child Support Enforcement has approved a IV–D State plan for each State. Federal regulations require States to amend their State plans only when necessary to reflect new or revised Federal statutes or regulations or material change in any State law, organization, policy, or IV–D agency operations. The requirement for submission of a State plan and plan amendments for the Child Support Enforcement program is found in sections 452, 454, and 466 of the Social Security Act.

Respondents: State IV–D Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Plan	54	8	0.50	216
OCSE–21–U4	54	8	0.25	108

Estimated Total Annual Burden Hours: 324.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–8666 Filed 4–11–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Statewide Automated Child Welfare Information System (SACWIS) Assessment Review Guide (SARG).

OMB No.: 0970–0159.

Description: For HHS to fulfill its obligation to effectively serve the nation's Adoption and Foster Care populations, and to report meaningful and reliable information to Congress about the extent of problems facing these children and the effectiveness of assistance provided to this population, the agency must have access to timely and accurate information about child welfare service populations and child welfare services. Section 476(b)of the Social Security Act requires that States submit statistical reports for child welfare populations, and Section 479 of the Act details State responsibilities to report specific information related to child abuse and neglect. CFR 1355.52 provides funding authority for statewide automated child welfare information systems (SACWIS) that meet Federal requirements for child welfare data collection. If a State chooses to implement a SACWIS, that system serves as the primary data source for Federal reporting. Currently, states use their SACWIS to support their efforts to meet the following Federal reporting requirements related to child welfare: the Adoption and Foster Care Analysis and Reporting System (AFCARS) required by section 479(b)(2) of the Social Security Act; the National Child Abuse and Neglect Data System (NCANDS); Child Abuse Prevention and Treatment Act (CAPTA); and the Chafee Independent Living Program's National Youth in Transition Database (NYTD). These systems also support state efforts to provide the information to conduct the Child and Family Service Reviews. Currently, forty-two States and the District of Columbia have developed, or are developing, a SACWIS with Federal financial participation.

45 CFR 1355.55 provides for continuing review, assessment and inspection of SACWIS. The purpose of this review is to determine whether the system, as described in the approved Advance Planning Document has been adequately completed and conforms to applicable regulations and policies.

To initiate a review, States complete and submit the SACWIS Assessment Review Guide (SARG) and other system documentation when they have completed system development and the system is operational statewide. The SARG template provides a format for State description of system functionality, operation, and outputs such as reports. The additional materials submitted as part of this process, such as system design documentation, are typically readily available to the State as a result of good project management practices.

The information collected in the SACWIS Assessment Review Guide will allow Federal reviewers to determine if the State's SACWIS meets the requirements for title IV–E Federal Financial Participation (FFP) defined at 45 CFR 1355.50, and that systems meet the goals and objectives of the approved Advance Planning Documents (APD) and conforms to the schedule, budget,

and other conditions of their approved APDs. Additionally, other States may be able to use the documentation provided as part of their preparation for the review process of their own system development efforts.

Respondents: Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SACWIS Assessment Review Guide	3	1	250	750

Estimated Total Annual Burden Hours: 750.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–8663 Filed 4–11–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–P–0256]

Determination That KEFLEX (Cephalexin) Capsule, Equivalent to 333 Milligrams Base, Was 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 KEFLEX (cephalexin) capsule, equivalent to (EQ) 333 milligrams (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for cephalexin capsule, EQ 333 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

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 approved 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, a drug is 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)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

KEFLEX (cephalexin) capsule, EQ 333 mg base, is the subject of NDA 050405 held by Victory Pharma, Inc., and the 333-mg strength was approved on May 12, 2006. KEFLEX is a cephalosporin antibiotic indicated for the treatment of respiratory tract infections caused by *Streptococcus pneumoniae* and *S. pyogenes,* as well as certain other infections caused by susceptible strains of certain designated micro-organisms as described in the product labeling.

KEFLEX (cephalexin) capsule, EQ 333 mg base, has never been marketed. In previous instances (*see* 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc., submitted a citizen petition dated May 29, 2009 (Docket No. FDA–2009–P–0256), under 21 CFR 10.30, requesting that the Agency determine whether KEFLEX (cephalexin) capsule, EQ 333 mg base, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that KEFLEX (cephalexin) capsule, EQ 333 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that KEFLEX (cephalexin) capsule, EQ 333 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of KEFLEX (cephalexin) capsule, EQ 333 mg base, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information