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]

BILLING CODE 4184–01–P

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Determination That KEFLEX (Cephalexin) Capsule, Equivalent to 333 Milligrams Base, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that KEFLEX (cephalexin) capsule, equivalent to (EQ) 333 milligrams (mg) base, was not withdrawn from sale for reasons of safety or effectiveness.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

that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list KEFLEX (cephalexin) capsule, EQ 333 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 KEFLEX (cephalexin) capsule, EQ 333 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: April 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8617 Filed 4–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Mellitus Interagency Coordinating Committee; Notice of Workshop

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a 2-day workshop on May 5, from 8 a.m. to 6 p.m., and May 6, from 7:30 a.m. to 4 p.m., at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The workshop will be open to the public, with attendance limited to space available. Non-Federal individuals planning to attend the workshop should register on the workshop Web site (*http://conferences.thehillgroup.com/NIDDK/DMICCworkshop/index.html*) at least 7 days prior to the workshop. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 10 days in advance of the workshop.

The DMICC facilitates cooperation, communication, and collaboration on diabetes among government entities. The May 5–6, 2011, DMICC workshop will discuss new and emerging opportunities for type 1 diabetes research supported by the Special Statutory Funding Program for Type 1 Diabetes Research.

Any interested person may file written comments with the Committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the workshop, there will not be time on the agenda for oral comments from members of the public.

An agenda for the DMICC workshop will be available on the following Web site: *http://conferences.thehillgroup.com/NIDDK/DMICCworkshop/index.html*. Members of the public who would like to receive e-mail notification about future DMICC meetings could register on a listserv available on the DMICC Web site: *http://www.diabetescommittee.gov*.

For further information concerning this workshop, contact Dr. Sanford Garfield, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 654, MSC 5460, Bethesda, MD 20892–5460, *Telephone:* 301- 594–8803 *Fax:* 301–402–6271, *E-mail: dmicc@mail.nih.gov*.

Dated: April 4, 2011.

Sanford Garfield,

Executive Secretary, DMICC, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, National Institutes of Health.

[FR Doc. 2011–8612 Filed 4–11–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Career Enhancement Award for Stem Cell Research.

Date: May 4, 2011.

Time: 12:30 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: William J. Johnson, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–435–0725, *johnsonwj@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 5, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8610 Filed 4–11–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The concept review and evaluation discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Folic Acid/Zinc Sulfate Supplementation, Semen Quality, and Ovulation Induction/IVF Outcomes.

Date: April 12, 2011.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate concept review.