Dated: February 26, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–4885 Filed 3–8–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Support Enforcement Program Expenditure Report (Form OCSE–396A) and the Child Support Enforcement Program Collection Report (Form OCSE–34A).

OMB No.: 0970–0181.

Description: State and Tribal agencies administering the Child Support Enforcement Program under Title IV–D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV–D agencies report quarterly expenditures and collections using Forms OCSE–396A and OCSE–34A, respectively. Tribal title IV–D agencies report quarterly expenditures using Form SF–269, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE–34A. The information collected on these reporting forms is used to compute quarterly grant awards to States and Tribes, the annual incentive payments to States and provides valuable information on program finances. This information is also included in a published annual statistical and financial report, available to the general public.

Under Public Law 111–5, the "American Recovery and Reinvestment Act of 2009" (ARRA), enacted in February 2009, the availability of Federal funding to State administered child support enforcement programs was substantially increased with a change in methodology of calculating these funds. We propose to formally incorporate this necessary revision into the quarterly expenditure report and to update the existing quarterly collection report to enable the same version of that form to be used by both State and Tribal IV–D agencies. We also propose to review other data entry elements and the accompanying instructions in both data collection forms to assure that the financial information requested from States and Tribes remains relevant and will assure that OCSE collects the information needed in the most efficient format feasible.

Respondents: State agencies (including the District of Columbia, Puerto Rico, Guam and the Virgin Islands) administering the Child Support Enforcement Program. Tribal agencies with approved plans to administer the Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396A	54	4	8	1,728
OCSE–34A	100	4	8	3,200

Estimated Total Annual Burden Hours: 4,928.

In compliance with the requirements of Section 506(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.

Dated: March 3, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–4895 Filed 3–8–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–P–0435 and FDA–2008–P–0554]

Determination That DOVONEX (Calcipotriene) Ointment, 0.005%, 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) is announcing its determination that DOVONEX (calcipotriene) Ointment, 0.005%, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcipotriene Ointment, 0.005%, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, rm. 6358, 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 (Public Law 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, 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)(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.

DOVONEX (calcipotriene) Ointment, 0.005%, is the subject of NDA 20–273, held by LEO Pharmaceutical Products Ltd. (LEO) and initially approved on December 29, 1993. DOVONEX is indicated for the treatment of plaque psoriasis in adults. In its annual report dated February 28, 2008, LEO notified FDA that DOVONEX (calcipotriene) Ointment, 0.005%, had been discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated July 25, 2008 (Docket No. FDA–2008–P–0435), under 21 CFR 10.30, requesting that the agency determine whether DOVONEX (calcipotriene) Ointment, 0.005%, was withdrawn from sale for reasons of safety or effectiveness. A second citizen petition was submitted by Mya Thomae Consulting, Inc., dated October 13, 2008 (Docket No. FDA–2008–P–0554), requesting that the agency determine whether DOVONEX (calcipotriene) Ointment, 0.005%, was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that DOVONEX (calcipotriene) Ointment, 0.005%, was not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that DOVONEX (calcipotriene) Ointment, 0.005%, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has 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 DOVONEX (calcipotriene) Ointment, 0.005%, 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 DOVONEX (calcipotriene) Ointment, 0.005%, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. 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: March 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–4925 Filed 3–8–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0108]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by May 10, 2010 **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993–0002, 301–796–0700, e-mail: *elizabeth.duvallmiller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers