Regulation citation	Number of respondents	Responses per respondent	Total responses	Hours per response (minutes)	Total burden hours	Wage rate	Total cost
60.3 Entity Registration—Update	13,115	1	13,115	5	1,092.92	25	27,323
60.13(a) Authorized Agent Designation—Initial	717	1	717	15	179.25	25	4,481.25
60.13(a) Authorized Agent—Update	139	1	139	5	11.58	25	289.50
60.14(c) Account Discrepancy Report	5	1	5	15	1.25	25	31.25
60.14(c) Electronic Funds Transfer Authorization	284	1	284	15	71	25	1,775.00
60.3 Entity Reactivation	0	0	0	0	0	0	0
Total	32,389		3,720,431		323,694.25		8,212,337.5

[1] Included in estimate for reporting adverse licensure actions to the HIPDB in 45 CFR Part 61.
[2] Included in estimate for hospital queries under § 60.12(a).
[3] Included in estimate for self queries to the HIPDB in 45 CFR Part 61.
[4] Voluntary queries—not required by law.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 15, 2010.

Sahira Rafiullah,

Director, Division of Policy Review and Coordination.

[FR Doc. 2010–6068 Filed 3–18–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: 45 CFR 303.7—Provision of Services in Interstate Child Support Enforcement Cases; Standard Forms.

OMB No.: 0970–0085.

Description: Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, amended 42 U.S.C. 666 to require State Child Support Enforcement (CSE) agencies to enact the Uniform Interstate Family Support Act (UIFSA) into State law by January 1, 1998. Section 311(b) of UIFSA requires the States to use standard Interstate forms, as mandated by Federal law. 45 CFR 303.7 also requires CSE programs to transmit child support case information on standard interstate forms when referring cases to other States for processing. During the OMB clearance process, we are taking the opportunity to make a minor revision to heading of Transmittals 1, 2, and 3. We have added the option for States to list the name of the country with which the petitioner or respondent is affiliated. The instructions for each of the Transmittal forms have also been updated to reflect this change.

Respondents: State agencies administering the Child Support Enforcement program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal 1	54	19,278	0.25	260,253
Transmittal 2	54	14,458	0.08	62,458.56
Transmittal 3	54	964	0.08	4,164.48
Uniform Petition	54	9,639	0.08	41,640.48
General Testimony	54	11,567	0.33	206,123.94
Affidavit Paternity	54	4,819	0.17	44,238.42
Locate Data Sheet	54	375	0.08	1,620
Notice of Controlling Order	54	964	0.08	4,164.48
Registration Statement	54	8,675	0.08	37,476

Estimated Total Annual Burden Hours: 662,139.36

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 will 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 16, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–6015 Filed 3–18–10; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0412]

Determination That HalfLytely and Bisacodyl Tablets Bowel Prep Kit (Containing 4 Bisacodyl Delayed Release Tablets, 5 Milligrams) Was 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 HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 milligrams (mg) (20-mg bisacodyl)) was withdrawn from sale for reasons of safety or effectiveness. The agency will not accept or approve abbreviated new drug applications (ANDAs) for bowel prep kits containing PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, 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 generally known 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.

On July 15, 2008, FDA received a citizen petition (Docket No. FDA–2008–P–0412), submitted under 21 CFR 10.30, from Foley & Lardner LLP. The petition requests that the agency determine whether HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg) (HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl)), manufactured by Braintree Laboratories, Inc. (Braintree), was withdrawn from sale for reasons of safety or effectiveness.

HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) (NDA 21–551) was approved on May 10, 2004. HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) was indicated for the cleansing of the colon as preparation for colonoscopy in adults. Braintree informed FDA that it ceased to manufacture and market HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) as of September 25, 2007. The drug product was then moved to the "Discontinued Drug Product List" section of the Orange Book.

FDA has reviewed its records concerning the withdrawal of HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl). FDA has also independently evaluated relevant literature, data from clinical trials, and reports of possible postmarketing adverse events. FDA has determined, under § 314.161, that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) was withdrawn from sale for reasons of safety or effectiveness.

Braintree discontinued this product containing a total dose of 20 milligrams of bisacodyl from sale after receiving approval from FDA on September 24, 2007, for HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 2 bisacodyl delayed release tablets, 5 mg (10-mg bisacodyl)). The data available from multiple clinical studies show that the HALFLYTLEY AND BISACODYL TABLETS BOWL PREP KIT (10-mg bisacodyl) has comparable effectiveness to the 20-mg product and has a safety advantage over the 20-mg product because there is less nausea and abdominal cramping in the patients treated with the 10-mg product. Furthermore, the 20-mg product may be associated with ischemic colitis.

FDA has also reviewed the latest approved labeling for the 20-mg product and has determined that it would need to be updated with additional safety information if Braintree were to reintroduce the 20-mg product to the market. FDA has determined that additional clinical studies of safety and efficacy would be necessary before HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) could be considered for reintroduction to the market. Accordingly, the agency will remove HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg) from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: March 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5979 Filed 3–18–10; 8:45 am]

BILLING CODE 4160–01–S