minimal to the states to provide the additional requested information.

Lastly, the request includes a survey for the sub-grantees (or CSBG-eligible entities). The survey focuses on the customer service that the CSBG sub-grantees receive from the CSBG grantees. The survey is optional, and this will be the fifth time that the CSBG sub-grantees that chose to submit will complete it. There are no revisions proposed to the survey.

Respondents: State governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories, and local level sub-grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
CSBG State Plan Application for States	56	3	31	5,208	1,736
CSBG Eligible Entity Master List	56	3	2	336	112
CSBG ACSI Survey of Eligible Entities	1007	1	.33	332	111

Estimated Total Annual Burden Hours: 1,848 hours for CSBG grantees; 111 for CSBG sub-grantees.

Comments: 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.

Authority: Sec. 676, Pub. L. 105–285, 112 Stat. 2735 (42 U.S.C. 9908).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–08604 Filed 4–23–21; 8:45 am]

BILLING CODE 4184–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Follow-Up Study of Coaching Practices in Early Care and Education Settings (OMB #0970–0515)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: This is a primary data collection request for the Follow-up Study of Coaching Practices in Early Care and Education Settings (Follow-up SCOPE), a follow-up to the previously approved Study of Coaching Practices in Early Care and Education Settings (SCOPE) survey (OMB #0970–0515). The study aims to examine, using surveys and qualitative interviews, the practice and processes of coaching and professional development in supporting early care and education (ECE) settings in their provision of care for preschool children and their families as COVID–19 has progressed. The study will focus on both centers and family child care (FCC) homes that serve low-income children, with a primary target of settings that serve children supported by Child Care and Development Fund subsidies or a Head Start grant.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: Follow-up SCOPE will examine the practice of coaching and professional development more broadly provided in support of centers and FCC homes. The study will collect information on the following: How coaching and professional development are supporting centers and FCC homes; the perceived value and role of coaching, professional development, and quality improvement; the features of coaching and how they are delivered; and the role(s) of coaches and how they have been supported. The study will also examine the degree to which coaching has been sustained and/or changed compared to before COVID–19. In particular, there will be a focus on understanding the use of remote versus in-person strategies for coaching and professional development. This study aims to explore the implementation of coaching and professional development in ECE settings as COVID–19 has progressed. The study will not allow for statistical generalization to different sites or service populations.

Survey and interview questions will focus on the current status of these activities at the time of the data collection, changes compared to before COVID–19 began, and what has been challenging or worked well. The study will use surveys and interviews with center directors, FCC providers, and coaches. The sample frame will be comprised of respondents to the 2019 survey.

Respondents: ECE center directors, coaches, and FCC providers who responded to 2019 SCOPE surveys.

ANNUAL BURDEN ESTIMATES

[Data collection will be completed within a one-year period]

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Coach Survey (Instrument 1)	100	1	.33	33
Center Director Survey (Instrument 2)	66	1	.33	22
FCC Provider Survey (Instrument 3)	38	1	.33	13
Coach Interview (Instrument 4)	12	1	.75	9
Center Director Interview (Instrument 5)	24	1	.75	18
FCC Provider Interview (Instrument 6): FCC providers	12	1	.75	9

Estimated Total Annual Burden Hours: 104.

Authority: 42 U.S.C. 9858(a)(5), 42 U.S.C. 9835, and 42 U.S.C. 9844.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–08614 Filed 4–23–21; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–P–2304]

Determination That Sodium Chloride 14.6% Solution for Injection, 50 Milliequivalent/20 Milliliters, in Plastic Containers, 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 or Agency) has determined that Sodium Chloride 14.6% solution for injection, 50 milliequivalent (mEq)/20 milliliters (mL), in plastic containers, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–4191, *Ayako.Sato@fda.hhs.gov.*

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 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.

Sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, is the subject of NDA 18897, held by Hospira Inc., and initially approved on July 20, 1984. Sodium chloride 14.6% solution for injection is indicated for use as an electrolyte replenisher in parenteral fluid therapy.

In a communication dated September 6, 2019, Hospira Inc. notified FDA that sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Fresenius Kabi USA, LLC submitted a citizen petition dated December 16, 2020 (Docket No. FDA–2020–P–2304), under 21 CFR 10.30, requesting that the Agency determine whether sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was withdrawn 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 sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list sodium chloride 14.6% solution for injection, 50 mEq/20 mL, in plastic containers, 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