departments. These data are routinely collected through the occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work). The second data source, for which NIOSH is seeking OMB approval, is responses to telephone interview surveys of the injured and exposed firefighters identified within NEISS-Work.

The proposed one-year extension of the telephone interview surveys will supplement NEISS-Work data with a description of firefighter injuries and exposures, including worker characteristics, injury types, injury circumstances, injury outcomes, and use of personal protective equipment (PPE). Previous reports describing occupational injuries and exposures to firefighters provide limited details on specific regions or sub-segments of the population. As compared to these earlier studies, the scope of the telephone interview data will be broader, as it includes sampled cases nationwide, and has no limitations regarding type of employment (*i.e.,* volunteer versus career). Results from telephone interviews will be analyzed and reported as a case series.

The sample size for the telephone interview survey is estimated to be approximately 35 firefighters annually. This is based on the current survey completion rate of about 11%. While this completion rate is lower than originally expected, the project team still expects to gain additional insight to injuries and exposures that firefighters incur.

The NIOSH Division of Safety Research (DSR) is conducting this project. DSR has a strong interest in improving surveillance of firefighter injuries and exposures, to provide the information necessary for effectively targeting and implementing prevention efforts, and consequently reducing occupational injuries and exposures to firefighters. The Consumer Product Safety Commission (CPSC) will also contribute to this project, as they are responsible for coordinating the collection of all NEISS-Work data, and for overseeing the collection of all telephone interview data.

NIOSH request approval for an estimated 18 burden hours annually. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Firefighters	Firefighter Follow-Back Survey	35	1	30/60	18
Total					18

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–21DJ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Assessment of a Training Program to Improve Continuity of Care for Children and Families Affected by Fetal Alcohol Spectrum Disorders (FASD) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 8, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate 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) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessment of a Training Program to Improve Continuity of Care for Children and Families Affected by Fetal Alcohol Spectrum Disorders (FASD)—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this information collection is to assess a curriculum for training pediatric residents to identify, refer and care for children with prenatal exposure to alcohol or a fetal alcohol spectrum disorder (FASD). The curriculum was developed by the

American Academy of Pediatrics (AAP) with support from CDC. The curriculum uses a Train-the-Trainer model whereby attending physicians at developmental continuity clinics receive in-depth training and then facilitate training of first-year pediatric residents in their own clinics.

In Phase One, training for attending physicians will be organized around four presentations by experts in the identification, diagnosis, and care of children with FASD and their families. Pre/post-test assessments will be obtained for each presentation, followed by an overall assessment at the end of the training day.

In Phase Two, the attending physicians will implement a curriculum of continuing medical education activities with their first-year pediatric residents. Required activities for residents include viewing three pre-recorded video presentations. Changes in residents' knowledge of training content will be assessed both before and after the video presentations.

Pre/post-test data will be collected through paper-and-pencil surveys for in-person training of attending physicians, and by secure email for resident trainees. Attending physicians will also be asked to participate in a final project debriefing conference call.

The purpose and use of the assessment data will be to assure that specific information in the FASD training curriculum is conveyed and understood by participants. The public health goal is to strengthen the identification, referral, and care of children with prenatal exposure to alcohol.

OMB approval is requested for three years. Approximately 10 clinics will be recruited each year. Respondents will be one attending physician per clinic, and approximately 25 pediatric residents per clinic. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 223 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)
Pediatrician (Attending Physician) ...	Attending Physicians Screening & Diagnosis Pretest ..	10	1	10/60
	Attending Physicians Screening & Diagnosis Posttest	10	1	10/60
	Attending Physicians Treatment Across Lifespan Pretest.	10	1	10/60
	Attending Physicians Treatment Across Lifespan Posttest.	10	1	10/60
	Attending Physicians Overcoming Social Attitudes Pretest.	10	1	10/60
	Attending Physicians Overcoming Social Attitudes Posttest.	10	1	10/60
	Attending Physicians Educational Care Pretest	10	1	10/60
	Attending Physicians Educational Care Posttest	10	1	10/60
	Attending Physicians Training Program Assessment ...	10	1	15/60
	Attending Physicians Overall Program Assessment	10	1	20/60
	Attending Physicians Debriefing Guide	10	1	1
	Attending Physicians Application (A15)	10	1	10/60
Pediatrician (Resident)	Resident Overall Effects & Prevalence Video Pretest	250	1	15/60
	Resident Overall Effects & Prevalence Video Posttest	250	1	15/60
	Resident Overall Program Assessment	250	1	15/60

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Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Cilastatin Sodium; Imipenem; Relebactam; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Draft Guidance for Cilastatin Sodium; Imipenem; Relebactam.'' The draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for cilastatin sodium; imipenem; relebactam for injection.

DATES: Submit either electronic or written comments on the draft guidance by September 17, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the