

(NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

It is estimated that each year roughly one in six Americans get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases, CDC and partners ensure rapid and coordinated surveillance, detection, and response to multistate outbreaks, to limit the number of illnesses, and to learn how to prevent similar outbreaks from happening in the future.

Conducting interviews during the initial hypothesis-generating phase of multistate foodborne disease outbreaks presents numerous challenges. In the U.S. there is not a standard, national form or data collection system for illnesses caused by many enteric pathogens. Data elements for hypothesis generation must be developed and agreed upon for each investigation. This process can take several days to weeks and may cause interviews to occur long after a person becomes ill.

CDC requests a revision to this project to collect standardized information, called the Standardized National Hypothesis-Generating Questionnaire, from individuals who have become ill during a multistate foodborne disease event. Since the questionnaire is designed to be administered by public health officials as part of multistate hypothesis-generating interview activities, this questionnaire is not

expected to entail significant burden to respondents.

The Standardized National Hypothesis-Generating Core Elements Project was established with the goal to define a core set of data elements to be used for hypothesis generation during multistate foodborne investigations. These elements represent the minimum set of information that should be available for all outbreak-associated cases identified during hypothesis generation. The core elements would ensure that similar exposures would be ascertained across many jurisdictions, allowing for rapid pooling of data to improve the timeliness of hypothesis-generating analyses and shorten the time to pinpoint how and where contamination events occur.

The Standardized National Hypothesis Generating Questionnaire was designed as a data collection tool for the core elements, to be used when a multistate cluster of enteric disease infections is identified. The questionnaire is designed to be administered over the phone by public health officials to collect core element data from case-patients or their proxies. Both the content of the questionnaire (the core elements) and the format were developed through a series of working groups comprised of local, state, and federal public health partners.

Since the last revision of the SNHGQ in 2016, ORPB has investigated over 700 multistate foodborne and enteric

clusters of infection involving over 26,000 ill people. Of which, an outbreak vehicle has been identified in 200 of these investigations. These outbreaks have led to over 50 recalls and countless regulatory actions that have removed millions of pounds of contaminated vehicles out of commerce. In almost all instances, the SNHGQ or iterations of the SNHGQ have been instrumental in the successful investigation of these outbreaks. The questionnaire has allowed investigators to more efficiently and effectively interview ill persons as they are identified. Because these exposures are captured in a common, standard format, we have been able to share and analyze data rapidly across jurisdictional lines. Faster interview response and analysis times have allowed for more rapid epidemiologic investigation and quicker regulatory action, thus helping to prevent thousands of additional illnesses from occurring and spurring industry to adopt and implement new food safety measures in an effort to prevent future outbreaks.

The total estimated annualized burden for the Standardized National Generating Questionnaire is 3,000 hours (approximately 4,000 individuals identified during the hypothesis-generating phase of outbreak investigations with 45 minutes/response). There are no costs 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)
Ill individuals identified as part of an outbreak investigation.	Standardized National Hypothesis Generating Questionnaire	4,000	1	3,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.
[FR Doc. 2020-03342 Filed 2-19-20; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Tribal Child Support Enforcement Direct Funding Request: 45 CFR 309-Plan (OMB #0970-0218)

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for Public Comment.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF) is requesting a 3-year extension of the 45

CFR 309-Plan (OMB #0970-0218, expiration 3/21/2020). There are no changes requested to this form.

DATES: Comments due within 30 days of publication. 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:

Desk Officer for the Administration for Children and Families. Copies of the proposed collection may be obtained by emailing infocollection@acf.hhs.gov. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The final rule within 45 CFR part 309, published in the **Federal**

Register on March 30, 2004, contains a regulatory reporting requirement that, in order to receive funding for a Tribal IV–D program a Tribe or Tribal organization must submit a plan describing how the Tribe or Tribal organization meets or plans to meet the objectives of section 455(f) of the Social Security Act, including establishing paternity; establishing, modifying, and enforcing support orders; and locating noncustodial parents. The plan is required for all Tribes requesting funding; however, once a Tribe has met the requirements to operate a comprehensive program, a new plan is

not required annually unless a Tribe makes changes to its title IV–D program. If a Tribe or Tribal organization intends to make any substantial or material changes, a Tribal IV–D plan amendment must be submitted for approval. Tribes and Tribal organizations must have an approved plan and submit any required plan amendments in order to receive funding to operate a Tribal IV–D program. This paperwork collection activity is set to expire in March 2020.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
45 CFR 309-Plan	60	1	120	7,200
45 CFR 309-New Plan	2	1	480	960

Estimated Total Annual Burden Hours: 8,160

Authority: 45 CFR 309.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–03354 Filed 2–19–20; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0626]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pulmonary-Allergy Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on April 21, 2020, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm.

1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–0626. The docket will close on April 20, 2020. Submit either electronic or written comments on this public meeting by April 20, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 20, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before April 7, 2020, will be provided to the committee. Comments received after

that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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 public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).