in scope. Some of the conditions listed in this section are contraindications or precautions to vaccination, while others are intended to prompt the patient and provider to ask additional questions and investigate further.

Section 4 (''Risks of a vaccine reaction'') sets forth adverse events that could occur after vaccination. Included are discussion of the risk of severe allergic reaction and the remote possibility of serious injury or death. Language for this section has been standardized across VISs to the extent possible while still adhering to vaccine-specific information from the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The complete text of section 5 (''What if there I a serious problem?''), section 6 (''The National Vaccine Injury Compensation Program''), and section 7 (''How can I learn more?''), as proposed, matches exactly across all of the vaccine information materials, except for the VIS for rotavirus vaccine which includes additional information related to the risk of intussusception (a very serious adverse event that is specific to rotavirus vaccine) in sections 5 and 6.

Text in all sections of the VISs is updated using plain language terms and concepts, and removing some of the more detailed numerical and statistical data, to make the documents more easily understandable to the general public. Because the vaccine information statements are intended for patient education, content that is relevant for providers but not for patients is removed. Language has been updated to reflect a provider-neutral approach, reflecting the fact that vaccines may be administered by medical professionals in a variety of specialty fields (*e.g.,* using the term ''health care provider'' instead of ''doctor'' or ''nurse'').

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials. Copies of the proposed vaccine information materials are available at *http://www.regulations.gov* (see Docket Number CDC–2021–0001). Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–00266 Filed 1–8–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0356]

Submission for OMB Review; Formative Data Collections for ACF Research and Evaluation

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

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) proposes to extend data collection under the existing overarching generic clearance for Formative Data Collections for ACF Research and Evaluation (OMB #0970–0356). There are no changes to the proposed types of information collection or uses of data, but the request does include an increase to the estimated number of respondents and, therefore, the overall burden estimate.

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 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: ACF programs promote the economic and social well-being of families, children, individuals, and communities. OPRE studies ACF programs, and the populations they serve, through rigorous research and evaluation projects. These include evaluations of existing programs, evaluations of innovative approaches to helping low-income children and families, research syntheses, and descriptive and exploratory studies. OPRE's research serves to provide further understanding of current programs and service populations, explore options for program improvement, and assess alternative policy and program designs. OPRE anticipates undertaking a variety of new research projects related to welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, family and youth services, home visiting, child welfare, and other areas of interest to ACF. Under this generic clearance, ACF engages in a variety of formative data collections with researchers, practitioners, technical assistance providers, service providers, and potential participants throughout the field to fulfill the following goals: (1) Inform the development of ACF research, (2) maintain a research agenda that is rigorous and relevant, (3) ensure that research products are as current as possible, and (4) inform the provision of technical assistance. ACF uses a variety of techniques including semi-structured discussions, focus groups, surveys, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Respondents: Example respondents include: key stakeholder groups involved in ACF projects and programs, state or local government officials, service providers, participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF research and programs, or others involved in conducting ACF research or evaluation projects.

ANNUAL BURDEN ESTIMATES

Instrument	Estimated total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Semi-Structured Discussions and Focus Groups	3,000	1	2	6,000
Interviews	1,500	1	1	1,500
Questionnaires/Surveys	1,125	1	.5	563

Estimated Total Annual Burden Hours: 8,063

Authority: Social Security Act, Sec. 1110 [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–00209 Filed 1–8–21; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2635]

Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is requesting comments on a document entitled ''Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper.'' The concept paper outlines a potential framework for how sponsors of new animal drug products containing medically important antimicrobial drugs approved for use in or on animal feed might voluntarily establish appropriately defined durations of therapeutic administration to food-producing animals where none currently exist. Establishing appropriately defined durations of use to mitigate development of antimicrobial resistance would be consistent with previous efforts by FDA to protect public health by promoting the judicious use of these drugs in food-producing animals.

DATES: Submit either electronic or written comments by April 12, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 12, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 12, 2021. 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.

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'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2635 for ''Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed: A Concept Paper.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the