Office of New Drugs (OND) led the development of two documents to facilitate internal review of safety data. The first document, ''FDA Medical Queries,'' provides a standardized approach to group preferred terms of adverse events using ''Medical Dictionary for Regulatory Activities'' (MedDRA) terminology. The second document, ''Standard Safety Tables and Figures Integrated Guide,'' provides standardized methods for visualization of clinical trial safety data into tables and figures. FDA values transparency and collaboration with external stakeholders; therefore, both documents are available for public comment through the docket.

II. Topics Discussed at the Public Workshop

At the public workshop entitled ''Advancing Premarket Safety Analytics Workshop,'' CDER's OND presented its work and perspective related to safety analytics. The workshop provided presentations from FDA staff on the two documents ''FDA Medical Queries'' and ''Standard Safety Tables and Figures Integrated Guide '' (meeting materials available at *https://healthpolicy.duke.edu/events/advancing-premarket-safety-analytics*). The workshop also included panel discussions with industry representatives on ''Stakeholder Perspectives Exploring Premarket Adverse Event Grouping'' and ''Examining Strategies for Adverse Event Analysis.'' FDA documents were intended as a starting point for broader discussions on best practices and innovative approaches for advancing premarket safety signal analytics. We are also seeking comment on the topics discussed at the workshop.

Dated: October 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23925 Filed 11–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Proposed Collection; Comment Request; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions associated with FDA's Federal-State Food Regulatory Program Standards.

DATES: Either electronic or written comments on the collection of information must be submitted by January 3, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2021–N–0341 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards.'' 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 ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Federal-State Food Regulatory Program Standards

OMB Control Number 0910–0760—Revision

This information collection supports FDA's Animal Food (formerly ''Feed'') Regulatory Program Standards (AFRPS) and Egg Regulatory Program Standards (ERPS). In the United States, Federal and State government agencies ensure the safety of human and animal food. FDA is responsible for ensuring that all human and animal food moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure human and animal food a produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of human and animal food facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect human and animal food.

The FDA Food Safety Modernization Act calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of human and animal food safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure credibility of human and animal food programs within the IFSS. The AFRPS and ERPS provide a uniform and consistent approach to animal food and egg regulation in the United States. Implementation of the AFRPS and ERPS are voluntary.

The AFRPS and ERPS are the frameworks that each State should use to design, manage, and improve its animal food or egg regulatory program. The AFRPS standards include the following: (1) regulatory foundation; (2) training program; (3) inspection program; (4) audit program; (5) animal food-related illnesses or death and emergency response; (6) compliance and enforcement program; (7) outreach program; (8) planning and resources; (9) assessment and improvement; (10) laboratory services; and (11) sampling program. The ERPS include equivalent standards for egg regulatory programs except they do not include a separate standard 11 sampling program. Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a state program voluntarily agrees to implement the standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard. We invite you to visit our website (*https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards*) for more information and to access the program standards.

Both the AFRPS and ERPS package include forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the AFRPS and ERPS must be maintained in good order by the state program and must be available to verify the implementation of each standard.

As set forth in the AFRPS and ERPS, the state program is expected to review and update its improvement plan on an annual basis. The state program completes an evaluation of its implementation status at least every 3 years following the baseline evaluation by reviewing and updating the self-assessment worksheets and required documentation for each standard. The evaluation is needed to determine if each standard's requirements are, or remain, fully met, partially met, or not met. The state program revises the improvement plan based upon this evaluation.

In collaboration with the State Governments, FDA recently completed a revision of the animal food program standards that incorporated the most current knowledge and lessons learned in the application of the 2020 AFRPS by State partners and program assessment by FDA. In an effort to improve program effectiveness, understanding and clarity, changes to the AFRPS include those to program definitions, all 11 program standards, appendices and assessment worksheets that may be used by the States who have adopted the AFRPS. Such changes include updates to terminology, most notably replacing the term ''animal feed'' with ''animal food'' consistent with the terminology of the FDA Food Safety Modernization Act, and minor editorial changes. Other changes include streamlining both the standards and appendices to be less prescriptive in nature and better focus on information capture needs. This process results in an overall reduction of 11 appendices (most of which provided more program specific guidance or examples and therefore are not expected to change the burden) and a reformatting of the remaining

appendices to be more uniform, succinct and tabular in structure. The revised program standards are the result of external collaboration and coordination between FDA and the Association of American Feed Control Officials (AAFCO) in which we consider any formal comments received on the 2020 edition of the program standards and feedback obtained from our collaboration with the States. A copy of the revised program standards is available in the docket.

Description of Respondents: Respondents are State Departments of Agriculture or Health enrolled in the AFRPS or ERPS (State Governments).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondents; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	1	25	569	14,225
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	1	10	569	5,690
Total	.....	.....	.....	.....	19,915

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondents; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with AFRPS	25	11	275	40	11,000
State, local, Territorial and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	10	100	40	4,000
Total	.....	.....	.....	.....	15,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

No change in burden is expected to be incurred with the implementation of the revised AFRPS. However, we have adjusted the number of respondents to the information collection associated with the AFRPS to reflect a reduction in enrollment since our last evaluation. In addition, based on the Agency's experience over the past 3 years, we have added reporting burden and adjusted the recordkeeping burden estimates associated with the AFRPS and ERPS, resulting in an increase in responses and burden hours.

Dated: October 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23919 Filed 11–2–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2107]

Cross Labeling Oncology Drugs in Combination Regimens; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Cross Labeling Oncology Drugs in Combination Regimens.'' This guidance describes FDA's current recommendations on including relevant information in labeling for oncology drugs approved for use in combination regimens. This guidance finalizes the draft guidance of the same title issued on November 20, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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