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]

BILLING CODE 4164–01–P

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

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2107 for ''Cross Labeling Oncology Drugs in Combination Regimens.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Marc Theoret, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2218, Silver Spring, MD 20993, 301–796–4099; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 (85 FR 74352). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarity on our recommendations for the content of each section of the prescribing information, including how doses or dosage modifications for any other drug in the combination regimen should be described in labeling.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cross Labeling Oncology Drugs in Combination Regimens.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314, including the submission of labeling in 21 CFR 314.50(e)(2)(ii) and (l)(1)(i) and the submission of new drug applications (NDAs) and supplemental NDAs, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 regarding the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information for the content and format of prescription drug labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in FDA's guidance entitled ''Formal Meetings Between FDA and Sponsors and Applicants for PDUFA Products'' have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23866 Filed 11–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Request for Public Comment on Two Draft Recommendations To Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Diabetes in Pregnancy and Screening for Type 2 Diabetes After Pregnancy

AGENCY: Health Resources and Services Administration, Department of Health and Human Services.

ACTION: Notice.