we have issued letters of enforcement discretion to 12 of them. We received letters from 11 of these respondents indicating their intent to bring their products fully into compliance with applicable regulatory requirements and requesting that we continue to exercise enforcement discretion in the interim, and have therefore adjusted the number of respondents associated with the corresponding activities accordingly. We assume each request requires an average of 5 hours to prepare, for a total of 55 burden hours (11 letters × 5 hours). We estimate these same respondents will then submit a compliance plan and assume each plan will require an average of 90 hours to prepare, for a total of 990 burden hours (11 plans × 90 hours).

We estimate the burden associated with the voluntary notification of positive sampling results as discussed in our March 8, 2023, letter to be 20 responses and 5 hours annually, assuming 15 minutes is necessary for the completion of this activity. We also assume respondents will utilize established notification methods found on our website or by contacting the FDA district office in which the positive sampling results have occurred.

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06249 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0110]

Clinical Trial Considerations To Support Accelerated Approval of Oncology Therapeutics; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' The purpose of this guidance is to provide recommendations to sponsors of anti-cancer drugs or biological products on considerations for designing trials intended to support accelerated approval. The accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. This guidance describes considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics.

DATES: Submit either electronic or written comments on the draft guidance by May 26, 2023 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 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–2023–D–0110 for ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' 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 the draft 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 to 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Fashoyin-Aje, Oncology Center of Excellence, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2352, Silver Spring, MD 20993, 240–402–0205; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7242, Silver Spring, MD 20993, 240–402–8113.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' The purpose of this guidance is to provide recommendations to sponsors of anti-cancer drugs or biological products on considerations for designing trials intended to support accelerated approval. The accelerated approval pathway is commonly used for approval of oncology drugs in part due to the serious and life-threatening nature of cancer and because of available surrogate or intermediate clinical endpoints considered reasonably likely to predict clinical benefit. Single-arm trial designs and response rate endpoints (with duration of response as supportive) have most commonly been used in oncology because response rate is a marker of drug activity since malignant tumors do not typically regress on their own, and response rate can be interpreted in single-arm trials for monotherapy drug regimens. However, there are limitations to the use of single-arm trials in support of accelerated approval, including but not limited to: small safety datasets, low magnitude response rates that may not be reasonably likely to predict clinical benefit, and the inability to establish differential contribution of effect for combination regimens. Additionally, the reliance on cross-trial comparisons to historical trials to assess whether the observed treatment effect represents an improvement over available therapy is challenging. These limitations add uncertainty to the assessment of the safety and/or effectiveness of a drug such that accelerated approval based on a single-arm trial may not be justified in a given clinical setting.

Given the limitations of single-arm trials, FDA considers a randomized controlled trial to be the most appropriate trial design to support accelerated approval of oncology drugs. When properly designed and executed, a randomized controlled trial provides a more robust efficacy and safety assessment and allows for direct comparisons to a concurrent control arm. Sponsors can, as appropriate, elect to conduct a single randomized controlled trial to support an accelerated approval and to verify clinical benefit (*i.e.,* follow the ''one-trial'' approach), or they can conduct separate trials—one to support the accelerated approval and another, a confirmatory trial, to verify clinical benefit. The ''one-trial'' approach maintains efficiency in drug development by providing early access to an investigational drug using the accelerated approval pathway, while ensuring that a postmarketing trial is fully accrued and well underway to verify longer term benefit in a timely fashion.

This guidance describes considerations for designing, conducting, and analyzing data for trials intended to support accelerated approval of oncology drugs. Specifically, the guidance provides recommendations addressing the design, conduct, and analyses of data for either two separate randomized controlled trials or for using the ''one-trial'' approach for accelerated approval. The guidance also provides recommendations for designing, conducting, and analyzing data from a single-arm trial intended to support accelerated approval (when appropriate), and the considerations for determining whether the data may be adequate for this purpose. Regardless of the approach under consideration, FDA recommends early discussion before study initiation and during trials, as appropriate.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.'' 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 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05910 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1027]

Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Questions and Answers About Dietary Guidance Statements in Food Labeling: