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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics.''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:

Draft Guidance for Industry.'' The draft guidance, when finalized, will provide FDA's current thinking on the use of Dietary Guidance Statements on packaged food labels and more broadly in the labeling of foods, including any written, printed, or graphic material accompanying a food, such as labeling on websites. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by June 26, 2023 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by June 26, 2023.

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–1027 for ''Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry.'' 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.'' We will review this copy, including the claimed confidential information, in our 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 Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450 or Denise See, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity. We are committed to accomplishing this by promoting healthy starts through improved maternal, infant, and child health, creating a healthier food supply for all, and empowering consumers with more informative and accessible labeling to choose healthier diets. One key component of this work focuses on claims and nutrition-related statements, such as Dietary Guidance Statements, on food labeling. Claims and Dietary Guidance Statements act as quick signals on the front of the package to help consumers, particularly consumers with lower nutrition or health literacy, better understand nutrition information. They also can encourage industry to reformulate products to create healthier options that consumers seek.

On July 26, 2018, we held a public meeting where we sought input on the

Agency's Nutrition Innovation Strategy (public meeting). Among other things, we sought input on: (1) what types of claims or other nutrition-related labeling statements are most helpful in facilitating product innovation to promote healthful eating patterns and (2) what types of claims and other labeling statements are most helpful to consumers in selecting foods consistent with recommendations in the ''Dietary Guidelines for Americans'' (Dietary Guidelines) (Ref. 1). The comments we received during the public meeting and to the public meeting docket (Docket No. FDA–2018–N–2381) from a variety of stakeholders, including industry, consumers, trade associations, and consumer groups, on the use of food labeling claims and statements demonstrated that there is a clear interest in labeling claims, statements, symbols, and vignettes that will allow consumers to determine how foods and food groups can contribute to nutritious dietary patterns. We considered those comments in the development of this draft guidance.

After the public meeting, we revisited prior work we had undertaken on the use of statements in food labeling that would signal to consumers how foods and food groups can contribute to nutritious dietary patterns that also informed the development of this draft guidance. For example, in December 2002, we announced our Consumer Health Information for Better Nutrition Initiative. The purpose of this initiative was to make available more and better information about conventional foods and dietary supplements to help consumers improve their health and decrease the risk of diet-related diseases by making sound dietary decisions. As part of this initiative, we established the Task Force on Consumer Health Information for Better Nutrition (the Task Force). The Task Force recommended that FDA seek opportunities to promote the development and use of Dietary Guidance Statements in food labeling to assist consumers to make better food choices and to establish healthier eating patterns. To further the goals of the Consumer Health Information for Better Nutrition Initiative, on November 25, 2003, we published an Advance Notice of Proposed Rulemaking (ANPRM) in the **Federal Register** (68 FR 66040) requesting comment on, among other things, the use of Dietary Guidance Statements in food labeling. Although the ANPRM also discussed various issues regarding health claims in the labeling of conventional foods and dietary supplements, this guidance document addresses only Dietary Guidance Statements used in the labeling of conventional foods because Dietary Guidance Statements are based on key or principal recommendations from consensus reports, and current consensus report recommendations encourage Americans to meet nutrient requirements through the consumption of whole foods (*e.g.,* fruits and vegetables).

We received 18 comments on the ANPRM from industry, trade associations, health professional organizations, consumer groups, and a Federal government agency in response to the ANPRM. Nutrition science has evolved as well as our thinking on Dietary Guidance Statements since we issued the ANPRM, so some comments we received on Dietary Guidance Statements are not relevant to the draft guidance. We considered the relevant comments in the development of this draft guidance.

Consistent with current nutrition science, we are working on multiple ways we can modernize our approach to claims and nutrition-related statements that focus on helping consumers understand which foods and food groups can contribute to a nutritious dietary pattern. The use of Dietary Guidance Statements (*e.g.,* fruits and vegetables are part of a nutritious dietary pattern) in food labeling is one such tool to provide consumers with information to further this understanding. To provide another tool to assist consumers in making informed choices that are consistent with a healthy dietary pattern, we are working on updating the definition for the implied nutrient content claim ''healthy.'' In the **Federal Register** of September 29, 2022, we issued a proposed rule entitled ''Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'.'' The proposed regulation, when finalized, would update the definition for the implied nutrient content claim ''healthy'' to specify when the claim can be used on human food products. The definition would revise the requirements for foods that can bear the claim. Consistent with the advances in nutrition science and evolution of dietary guidance, specifically the Dietary Guidelines for Americans, 2020–2025 (Dietary Guidelines, 2020–2025) (Ref. 2), the proposed framework for the updated definition of the ''healthy'' claim uses a food group-based approach in addition to nutrients to limit. The proposed, updated ''healthy'' claim criteria emphasize healthy dietary patterns by requiring that food products contain a certain amount of food from at least one of the food groups or subgroups recommended by the Dietary Guidelines, 2020–2025. The proposed regulation would also require a food product to be limited in certain nutrients, including saturated fat, sodium, and added sugars. The proposed rule would also add certain recordkeeping requirements for foods bearing the claim where compliance cannot be verified through information on the product label.

The Dietary Guidelines is developed jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) and provides recommendations on healthy eating and the consumption of foods from various food groups, as well as the intake of specific macronutrients, such as saturated fats and added sugars, and micronutrients such as vitamins and minerals. They are developed every 5 years and are informed by the recommendations of a panel of experts called the Dietary Guidelines Advisory Committee. The Dietary Guidelines is based on the preponderance of current scientific and medical knowledge, and they currently provide Federal recommendations for healthy dietary patterns for Americans. They serve as the foundation for Federal nutrition policy. Although the Dietary Guidelines is issued every 5 years, and while the emphasis on dietary patterns has evolved, the underlying recommendations have largely remained consistent since the first edition was released in 1980, such as limiting intake of saturated fat, sodium, and sugars, and consuming foods with adequate amounts of fiber (Ref. 1). The Dietary Guidelines is designed for nutrition and health professionals to help all individuals and their families consume a healthy, nutritionally adequate diet. The Dietary Guidelines is the foundation of Federal nutrition guidance and are intended to inform policymakers when they implement Federal policies and programs related to food, nutrition, and health. The Dietary Guidelines, in addition to other consensus reports and scientific information, helps FDA to shape regulations on nutrition-related claims and other information that is permitted on a food label.

The Dietary Guidelines, 2020–2025 includes recommended amounts of food from food groups found in three different healthy dietary patterns: the Healthy U.S.-Style Dietary Pattern, the Healthy Mediterranean-Style Dietary Pattern, and the Healthy Vegetarian Dietary Pattern (Ref. 2). All three healthy dietary patterns provide intake

recommendations for the following food groups: vegetables, fruits, grains, dairy, protein foods, as well as oils. (The Dietary Guidelines, 2020–2025 does not refer to oils as a ''food group,'' but it emphasizes oils as part of a healthy dietary pattern. In the draft guidance, we refer to oils as a food group). We have used information from the Healthy U.S.-Style Dietary Patterns when developing recommendations for the amount of the food or category of food that is the subject of the statement that a product should contain if it bears a Dietary Guidance Statement (referred to as meaningful amounts or food group equivalents). We have also based our recommendations for the amount of sodium, saturated fat, and added sugars that a product should not exceed if it bears a Dietary Guidance Statement on key recommendations from the Dietary Guidelines, 2020–2025.

This draft guidance provides recommendations on how and when manufacturers should use key or principal recommendations from consensus reports, such as the Dietary Guidelines, as the basis for labeling statements that represent or suggest that an individual food or food group may contribute to or help maintain nutritious dietary patterns. We consider these types of labeling statements to be ''Dietary Guidance Statements.'' The draft guidance defines Dietary Guidance Statements and provides information to help industry determine how they may use Dietary Guidance Statements to make consumers aware of how their product contributes to a nutritious dietary pattern. In addition, we provide recommendations for the source of the Dietary Guidance Statement, the amount of the food or food group that is the subject of the statement that a product should contain (''meaningful amount'' or ''food group equivalent'') if it bears a Dietary Guidance Statement, and the amount of sodium, saturated fat, and added sugars that a product should not exceed if it bears a Dietary Guidance Statement. These recommendations are based upon current nutrition science and dietary recommendations, such as the Dietary Guidelines, 2020–2025 (Ref. 2). While our draft guidance encourages the consumption of whole grains consistent with nutrition science and Federal dietary guidance, we request comment on the use of Dietary Guidance Statements on refined grains that are staples of cultural cuisines that are not high in added sugars, saturated fat, and sodium. In addition, while our draft guidance provides recommendations for how to calculate ''meaningful amounts'' or ''food group equivalents'' of a food or food group that is the subject of the Dietary Guidance Statement, we request comment on other possible options to help ensure products bearing Dietary Guidance Statements contain meaningful amounts of recommended foods or food groups so that consumers can be assured that the product bearing the statement contributes to a nutritious dietary pattern, when consumed. Further, as discussed in the draft guidance, in situations when a food is recommended by a consensus report as part of a nutritious dietary pattern and the food has a nutrient profile that exceeds the recommended nutrient levels set forth in the guidance, we continue to find it appropriate for such a product to bear a Dietary Guidance Statement. However, when products exceed a recommended nutrient level set forth in the guidance, we recommend that these products bear a disclosure statement about the recommended nutrient level(s) it exceeds. We are seeking comment on the disclosure statement recommendations. Lastly, we are seeking comment on whether we should include recommendations in this guidance for the use of dietary guidance statements on bottles or containers of plain water and other calorie-free beverages (*e.g.,* flavored carbonated water, coffee, and tea).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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.

Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry

OMB Control Number 0910–0381

This draft guidance provides recommendations on how and when manufacturers may use Dietary Guidance Statements for labeling statements that represent or suggest that an individual food or food group may contribute to or help maintain nutritious dietary patterns. The draft guidance provides information to help industry determine how they may use Dietary Guidance Statements in labeling to make consumers aware of how their product contributes to a nutritious dietary pattern. As an option, the draft guidance provides recommendations for a product that may include a statement on its label near or adjacent to the Dietary Guidance Statement that tells consumers the amount of the food or food group that is the subject of the Dietary Guidance Statement present in one serving of the product (also known as ''Food Group Equivalent Statements''). In addition, for foods that exceed a recommended nutrient level set forth in this guidance, the draft guidance provides recommendations that these products bear a disclosure statement about the recommended nutrient level(s) it exceeds.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [1] [2]
Labeling following recommendations in "Questions and Answers About Dietary Guidance Statements in Food Labeling"	556	4	2,224	1	2,224	$3,422,736

[1] One time relabeling costs.
[2] There are no operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar labeling programs. We estimate that each year 556 manufacturers will relabel their products following recommendations found in the draft guidance. This estimate assumes manufacturers will remove Dietary Guidance Statements from their labels following recommendations in the draft guidance, as well as those that will add Dietary Guidance Statements to their labels. We estimate that each manufacturer will relabel 4 products for 2,224 total annual disclosures (556 manufacturers × 4 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 2,224 hours (2,224 disclosures × 1 hour). We estimate that there will be an annual capital cost of $3,422,736 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. HHS and USDA. 1980 Dietary Guidelines for Americans. February 1980. Available at: *https://health.gov/dietaryguidelines/1980.asp.*
2. HHS and USDA. Dietary Guidelines for Americans, 2020–2025. 9th Edition. December 2020. Available at: *https://www.dietaryguidelines.gov/.*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06304 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–D–1118 and FDA–2020–D–1138]

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency; Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff; 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 entitled ''Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.'' FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID–19 public health emergency (PHE) to ''normal operations.'' To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing this guidance to describe FDA's general recommendations for a phased transition process with respect to devices that fall within certain enforcement policies issued during the COVID–19 PHE declared by the Secretary of Health and Human Services (the Secretary) under the Public Health Service Act (PHS Act), including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices. This guidance applies to devices that fall within enforcement policies in guidances included in List 1 of this guidance. The phased transition process outlined in this guidance will begin on the ''implementation date.'' The implementation date is the day the PHE expires or 45 days after the finalization of this guidance, whichever comes later. Because the COVID–19 section 319 PHE declaration is anticipated to expire at least 45 days after the finalization of this guidance, or May 11, 2023, the implementation date is that date. The guidances in List 1 of this guidance will no longer be in effect after the 180-day transition period ends.

DATES: The announcement of the guidance is published in the **Federal Register** on March 27, 2023.

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