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–2018–D–3092 for ''Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products.'' 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.

- 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.gpo.gov/fdsys/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.

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: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0489; 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 ''Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products.'' This guidance provides recommendations to industry about using placebos and blinding in randomized controlled clinical trials in development programs for drug or biological products to treat hematologic malignancies and oncologic diseases regulated by CDER and CBER.

This guidance finalizes the draft guidance entitled ''Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development'' (August 24, 2018, 83 FR 42902). Changes made to the guidance took into consideration comments received on the draft guidance and include the following: (1) Clarifying that unblinding should be limited to only the patient and the investigator, (2) clarifying that the guidance does not address statistical approaches to consider when unblinding data, (3) making minor wording changes throughout the document for clarity, and (4) simplifying the guidance title.

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 ''Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 (Investigational New Drug Application) has been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

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,* or *https://www.regulations.gov.*

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18715 Filed 8–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2381]

Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is

announcing a public meeting entitled ''Horizontal Approaches to Food Standards of Identity Modernization.'' The purpose of the public meeting is to give interested persons an opportunity to discuss FDA's effort to modernize food standards of identity (SOI) and provide information about changes we could make to existing SOI, particularly changes that could be made across categories of standardized foods (*i.e.,* horizontal changes), to provide flexibility for the development of healthier foods. We are also interested in discussing horizontal changes that would better facilitate innovation. This effort is part of the FDA's comprehensive, multiyear Nutrition Innovation Strategy (NIS) designed to improve healthy dietary behavior and help reduce preventable death and disease related to poor nutrition by, among other things, providing incentives for food manufacturers to produce products that have more healthful attributes.

DATES: The public meeting will be held on September 27, 2019, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting notice and request for comments by November 12, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852. For more information on the hotel see *http://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html.*

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 November 12, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 12, 2019. 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–2018–N–2381 for ''Horizontal Approaches to Food Standards of Identity Modernization.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting or to register by phone: Mark Gifford, SIDEM, 1775 Eye St. NW, Suite 1150, Washington, DC 20006, telephone: 240–393–4496, Fax: 202–495–2901, email: *EventSupport@sidemgroup.com.*

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1731, email: *Juanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

On January 11, 2018, FDA released its 2018 Strategic Policy Roadmap (*https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm*), which focuses, in part, on efforts to empower consumers to make better and more informed decisions about their diets and health, foster the development of healthier food options, and expand the opportunities to use nutrition to reduce morbidity and mortality due to chronic disease. The roadmap highlights FDA's commitment to finding approaches to advance policies that better achieve these goals.

On March 29, 2018, the Commissioner of Food and Drugs announced a comprehensive, multiyear FDA Nutrition Innovation Strategy

(hereinafter the ''NIS'') (to access the speech, visit *https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm*). The NIS focuses, among other things, on providing incentives for food manufacturers to produce products that have more healthful attributes. Under the NIS, FDA is seeking to modernize food SOI in a manner that will achieve three primary goals: (1) Protect consumers against economic adulteration; (2) maintain the basic nature, essential characteristics, and nutritional integrity of food; and (3) promote industry innovation and provide flexibility to encourage manufacturers to produce more healthful foods. To inform this effort, we seek information from interested stakeholders to learn what changes have occurred in food production and manufacturing that impact industry's ability to comply with current SOI regulations and what we should be aware of when reviewing and exploring how to modernize our SOI regulations. We are also interested in learning whether we can achieve our SOI modernization goals in ways that produce cost savings.

Many foods have definitions and SOI established by law. FDA began establishing SOI to promote honesty and fair dealing in the interest of consumers shortly after the Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted in 1938. Since then, we have established more than 280 SOI for a wide variety of food products. SOI typically set forth permitted ingredients, both mandatory and optional, and sometimes specify the amount or proportion of each ingredient. Many SOI also designate the method of production. A food is misbranded if it purports to be or is represented as a food for which a SOI has been established but fails to conform to the standard. See 21 U.S.C. 343(g). Because we issued many SOI decades ago, various stakeholders have expressed concerns that many SOI are out of date and may impede innovation, including the ability to produce healthier foods.

SOI protect consumers against economic adulteration and reflect consumers' expectations about food. They may also describe the basic nature and essential characteristics, including nutritional characteristics, of the food (see FDA's May 20, 2005, proposed rule entitled, ''Food Standards; General Principles and Food Standards Modernization'' (70 FR 29214) for a discussion of the ''basic nature'' and ''essential characteristics'' of food). As consumers continue to seek more nutritious and healthful food options, we seek to ensure that SOI meet these expectations. Modernizing SOI can give manufacturers the flexibility to improve the nutrition and healthfulness of standardized foods, promote honesty and fair dealing in the interest of consumers, and help achieve the goals of the NIS.

On July 26, 2018, FDA held a public meeting to discuss the NIS (including SOI modernization) and give interested parties an opportunity to provide input. During the public meeting, many participants expressed general support for FDA exploring modernization options that could promote changes across all, or broad categories of, SOI to facilitate innovation and flexibility to reformulate products to produce more nutritious foods. Several participants highlighted that rapid advances in technology and science necessitated revisions to certain SOI. The participants, however, also stated that updating individual standards (some stakeholders have referred to this as a ''vertical'' approach) would be time-consuming and may not be feasible given FDA's limited resources. They proposed that a horizontal approach that permits additional flexibility across all or broad categories of standardized foods could help resolve this issue by allowing FDA to efficiently make comprehensive changes that could impact many standardized foods. For example, several participants cited FDA's regulation entitled, ''Requirements for foods named by use of a nutrient content claim and a standardized term'' (21 CFR 130.10) as a potential model. This regulation provides for modified versions of certain standardized foods that bear descriptive names that are meaningful to consumers (*e.g.,* ''fat free'' and ''low calorie''). Some participants also said we should consider consumer demand for healthful and nutritious foods as we explore how to modernize in ways that will allow food manufacturers to produce more nutritious food options. The NIS public meeting docket closed on October 11, 2018, and resulted in more than 5,000 comments. We have reviewed the comments and are using information provided to inform our strategy moving forward.

There has been broad interest from stakeholders regarding horizontal approaches to SOI modernization. Some offered concrete proposals about the design and content of a regulation that creates a horizontal standard to advance SOI modernization. For example, in October 2006, the Grocery Manufacturers Association (GMA) submitted a Citizen Petition asking FDA to amend 21 CFR part 130 to modernize food standards (see Docket ID: FDA–2007–P–0463–0367). The Citizen Petition identified six categories of variations from food standards that GMA believed should be permitted to provide flexibility. Several comments submitted to the NIS docket cited variations outlined in the GMA Citizen Petition as examples of horizontal standard options we should consider as part of SOI modernization.

To maximize our limited resources, we must consider efficient modernization approaches that will have the greatest potential impacts. As such, we are interested in learning more about horizontal approaches to SOI modernization that will encourage production of healthier foods and/or facilitate innovation, specifically allowing for use of new technologies and new or novel ingredients. We believe this focus supports the NIS goals of reducing the burden of chronic disease through improved nutrition. Furthermore, this will allow FDA to provide manufacturers with additional flexibility without adversely impacting the basic nature and essential characteristics of standardized foods.

FDA is issuing this request for comment and will hold a public meeting on September 27, 2019, to gather data and information from stakeholders regarding horizontal approaches to SOI modernization.

B. Legal Authority

Our authority to establish food standards is set forth in section 401 of the FD&C Act (21 U.S.C. 341). Section 401 of the FD&C Act authorizes us to issue regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container when such action promotes honesty and fair dealing in the interest of consumers. The standards of identity, quality, and fill of container for foods regulated by FDA are codified in 21 CFR parts 130 to 169. FDA food standards are established under the common or usual name of a food.

II. Topics for Discussion at the Public Meeting

The public meeting will explore horizontal approaches to SOI modernization that will support the goals of the NIS. We are interested in learning more about horizontal changes that would improve the nutrition or healthfulness of standardized foods and/or provide for flexibility and innovation in their production. We are considering all horizontal approaches that will ensure the basic nature and

essential characteristics of food are maintained. We also invite comment on how these changes could be efficiently accomplished. For example, we would like to know whether horizontal SOI might be a means for implementing the changes and how such standards could be structured.

The public meeting will begin with a plenary session, followed by breakout sessions that will discuss key topics relating to horizontal approaches to SOI modernization. Approximately 2 weeks before the meeting, we will post the public meeting agenda and additional background materials on the internet at: *https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.* In addition to the opportunity to comment at the public meeting, there will be an opportunity for interested stakeholders to submit written comments following the meeting (see **DATES**).

The first breakout session will explore nutrition topics. We are interested in learning what changes to existing SOI would encourage production of more nutritious foods. We are interested in hearing stakeholder perspectives regarding the role of nutrition in SOI modernization and how a horizontal approach to modernization could encourage production of more nutritious foods. We want to learn if current SOI pose barriers to production of more nutritious foods and, if so, understand how horizontal changes to standardized foods could help overcome these barriers. We also invite comments regarding how we could design a horizontal standard to provide manufacturers of standardized foods with the flexibility to reflect future advances in science and technology as they relate to improved nutrition.

The second breakout session will discuss issues related to innovation and what horizontal approaches to modernization could better accommodate advances in science and technology. We are interested in learning how horizontal changes could provide the flexibility necessary to accommodate future industry innovation while ensuring standardized foods continue to meet consumer expectations and maintain the basic nature and essential characteristics of food. We are particularly interested in learning about horizontal changes to manufacturing processes and permitted ingredients that could promote innovation. We request that comments indicate the foods to which a proposed horizontal change would apply, the current requirement(s) in the SOI to which the change would apply, and the specific change requested (*e.g.,* additional manufacturing processes permitted or ingredients permitted).

The third breakout session will discuss issues related to consumer expectations and standardized foods. We are interested in learning what flexibility we can provide in a horizontal approach to modernization, while ensuring standardized foods continue to meet consumer expectations. We want to learn about consumers' shifting expectations and how horizontal changes could allow innovation and product reformulation to meet such demands. For example, comments to the NIS public meeting docket highlighted that consumers now demand healthier foods and products that meet specific dietary needs (*e.g.,* ''gluten free'' products). As SOI are issued to ''promote honesty and fair dealing in the interest of consumers,'' we believe the consumer perspective is critical to understanding what flexibility we should consider when exploring horizontal changes to current SOI and invite comments on what, if any, limitations are appropriate to ensure standardized foods continue to meet consumer expectations.

We will consider all comments made at this public meeting or received through the docket (see **ADDRESSES**) as we consider how horizontal changes could support our SOI modernization goals. Information concerning the FDA's NIS and more information on our work to modernize SOI can be found at *https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting must register by 11:59 p.m. on September 20, 2019. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Juanita Yates (see **FOR FURTHER INFORMATION CONTACT**) no later than September 12, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. We urge individuals and organizations with common interests to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by September 12, 2019. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Persons attending FDA's public meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the public meeting: This public meeting will also be webcast. Webcast participants are asked to preregister at *https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*

Dated: August 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18713 Filed 8–28–19; 8:45 am]

BILLING CODE 4164–01–P