• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* DHAP Guideline Team, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS D21, Atlanta, Georgia 30329.

Instructions: All submissions must include the agency name and Docket Number. All relevant comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Priya Jakhmola, Health Scientist, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D21, Atlanta, Georgia 30329. Telephone: 404–639–2495, Email: *dhapguideline@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on opt-out routine HIV testing, including, but not limited to:

- Suggestions for revisions, edits, and new additions
- Contemporary issues and new evidence
- Implementation barriers, challenges, and lessons learned
- Examples of innovative models, partnerships, and collaborations

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information, inappropriate language, or examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final document and may revise the final document as appropriate.

Background

The CDC guideline ''Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings'' was published on September 22, 2006 in CDC's *Morbidity and Mortality Weekly Report* (MMWR). Since then, there have been changes in evidence related to HIV testing technologies and interventions, disease epidemiology, outcomes, implementation resources, and related guidelines. This evidence will be identified, assessed, and analyzed to inform the update.

CDC will update the 2006 Guidelines based on input from subject matter experts, public health agencies, the public, and other stakeholders. The guideline development process will draw on up-to-date nationally and internationally accepted guideline development criteria, tools, and resources, including CDC guideline development standards. The process will include a rigorous systematic review of key questions formulated through the PICO (Patient-Intervention-Comparator-Outcome) method. PICO is the foundation of an evidence-based process and facilitates the search for relevant evidence by identifying key concepts and formulating a search strategy. Graded recommendations will be developed using quality and strength of underlying evidence.

Throughout the process of updating the guideline, there will be multiple opportunities for the public to comment on the drafts. We welcome input from a diverse range of perspectives, which will inform the development of the guideline, improve its credibility, and increase the transparency of the process.

Dated: August 26, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–18659 Filed 8–28–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3092]

Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products; 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 ''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 the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (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'' issued August 24, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on August 29, 2019.

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–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