(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 parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 58 for good laboratory practices for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 312 that support FDA's regulations for investigational new drug applications 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.

The collections of information in biologics license applications submitted under 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

The collections of information in the guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' (available at *https://www.fda.gov/media/116754/download*) have been approved under OMB control number 0910–0733. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/media/86377/download*) have been approved under OMB control number 0910–0765.

The collections of information in the International Council for Harmonisation guidance for industry entitled ''E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)'' (available at *https://www.fda.gov/media/93884/download*) have been approved under OMB control number 0910–0843. The collections of information in the guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (available at *https://www.fda.gov/media/109951/download*) have been approved under OMB control number 0910–0429.

The collections of information regarding evaluation of the program for enhanced review transparency and communication for new molecular entity new drug applications and original biologics license applications in the Prescription Drug User Fee Act have been approved under OMB control number 0910–0746.

The collections of information described in the guidance for industry and review staff entitled ''Formal Dispute Resolution: Sponsor Appeals Above the Division Level'' (available at *https://www.fda.gov/media/126910/download*) have been approved under OMB control number 0910–0430.

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: February 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04397 Filed 3–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3292]

Master Protocols: Efficient Clinical Trial Design Strategies To Expedite Development of Oncology Drugs and Biologics; 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 ''Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics.'' This guidance provides advice to sponsors of drugs and biologics for cancer treatment regarding the design and conduct of clinical trials, other than first-in-human trials, intended to simultaneously evaluate more than one investigational drug and/or more than one cancer type within the same overall trial structure (master protocols) in adult and pediatric cancers. In contrast to traditional trial designs, where a single drug is tested in a single disease population in one clinical trial, master protocols use a single infrastructure, trial design, and protocol to simultaneously evaluate multiple drugs and/or disease populations in multiple substudies, allowing for efficient and accelerated drug development.

DATES: The announcement of the guidance is published in the **Federal Register** on March 2, 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–2018–D–3292 for ''Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics.'' 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 to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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: Lee Pai-Scherf, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2314, Silver Spring, MD 20993, 301–796–3400; 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 final guidance for industry entitled ''Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics.''

This guidance provides recommendations to sponsors of drugs or biologics for the treatment of cancer regarding the design and conduct of clinical trials intended to simultaneously evaluate more than one investigational drug and/or more than one cancer type within the same overall trial structure (master protocols) in adult and pediatric cancers. In general, the recommended phase 2 dose should have been established for an investigational drug or drugs evaluated in a master protocol. It also describes aspects of master protocol designs and trial conduct and related considerations, such as biomarker codevelopment and statistical analysis considerations, and provides advice on the information that sponsors should submit to FDA and on how sponsors can interact with FDA to facilitate efficient review.

This guidance does not address all issues relating to clinical trial design, statistical analysis, or the biomarker development process. Those topics are addressed in the International Council for Harmonisation (ICH) guidances for industry ''E9 Statistical Principles for Clinical Trials'' and ''E10 Choice of Control Group and Related Issues in Clinical Trials'' and the guidance for industry and FDA staff ''In Vitro Companion Diagnostic Devices.''

This guidance finalizes the draft guidance of the same name issued on October 1, 2018 (83 FR 49398). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include adding information about a dose-finding or safety lead-in component in basket trials when evaluating an investigational drug combination and comparison between experimental arms in umbrella trials and acceptable statistical approaches. Revisions were also made to various sections of the draft guidance to clarify the information to be submitted to FDA to support amendments to expand the protocol, the frequency of cumulative safety updates, the role of ad hoc institutional review board meetings, the role of the safety assessment committee, and informed consent requirements.

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 ''Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics.'' 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 314.50(d)(5) (clinical data section) and (d)(6) (statistical section) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312, subpart B, for the submission of investigational new drug applications (INDs), including protocols, protocol amendments, and information amendments, have been approved under OMB control number 0910–0014. Sponsors may request comment and advice on an IND as well as request meetings with FDA under 21 CFR part 312, subpart C (OMB control number 0910–0014).

The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in parts 50 and 56 for the protection of human subjects and institutional review boards have been approved under OMB control numbers 0910–0130; Responsibilities of sponsors and investigators (21 CFR part 312, subpart D) are also covered under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under

OMB control number 0910–0338; the collections of information in §§ 201.56 and 201.57 for the content and format requirements for labeling of human prescription drug and biological products have been approved under OMB control number 0910–0572.

In addition, the following collections of information in FDA's guidances have been approved by OMB (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents*):

- Collections in FDA's draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors and Applicants for PDUFA Products'' have been approved under OMB control number 0910–0429.
- Collections in FDA's guidance for industry entitled ''Special Protocol Assessment'' have been approved under OMB control number 0910–0470.
- Collections in FDA's guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581.
- Collections in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733.
- Collections in FDA's guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.
- Collections in FDA's guidance for industry entitled ''E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)'' have been approved under OMB control number 0910–0843.

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: February 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04398 Filed 3–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Vaccines Federal Implementation Plan

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Infectious Disease and HIV/AIDS Policy.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services' Office of Infectious Disease and HIV/AIDS Policy in the Office of the Assistant Secretary for Health announces that the draft *Vaccines Federal Implementation Plan 2021–2025* is available for public comment. The *Vaccines Federal Implementation Plan* is a companion document to the *Vaccines National Strategic Plan 2021–2025* (VNSP), which was published in January 2021. The *Vaccines Federal Implementation Plan* is a compilation of federal agency immunization activities that collectively advance the goals of the VNSP. Its target audience is other federal agencies and external partners who work in the area of vaccination. The public will be interested in how the implementation plan documents federal agency efforts. It does not outline mandates or other COVID–19 response measures.

DATES: The public comment period for the Vaccines Federal Implementation Plan starts on February 28, 2022 at 9 a.m. ET and ends on March 29, 2022 at 5 p.m. ET. All comments must be received by 5 p.m. ET on March 29, 2022 to be considered.

ADDRESSES: All comments must be submitted electronically to *nvp.rfi@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: David Kim, MD, MA, Director, Division of Vaccines, Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L616, Switzer Building, 330 C St. SW, Washington, DC 20024. Phone: 202–795–7697; Email: *nvp.rfi@hhs.gov.*

Dated: February 17, 2022.

David Kim,

Designated Federal Officer, Vaccines Federal Implementation Plan, Office of the Assistant Secretary for Health.

[FR Doc. 2022–04327 Filed 3–1–22; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted and registration is required to present oral comments.

DATES:

Meeting: Scheduled for April 19, 2022, 12:30 p.m.–2:00 p.m. Eastern Standard Time (EST). Ending times are approximate; meeting may end earlier or run later.

Written Public Comment Submissions: Deadline is April 12, 2022.

Registration for Oral Comments: Deadline is April 12, 2022.

ADDRESSES:

Meeting Web Page: The preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.nih.gov/go/165* by March 14, 2022.

Virtual Meeting: The URL for viewing the virtual meeting will be provided on the meeting web page the day before the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for the BSC, Office of Policy, Review, and Outreach, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3209, Fax: 301–451–5759, Email: *wolfe@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations on a contract concept: Bioinformatics Support for the NIEHS. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (*https://ntp.niehs.nih.gov/go/165*) or