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.

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Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: *Regarding tracers used in animal food:* Diego Paiva, Center for Veterinary Medicine (HFV–229), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240–402–6785, *Diego.Paiva@fda.hhs.gov; regarding tracers used in animal drug products:* Rebecca Owen, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–402–0670, *Rebecca.Owen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #258 entitled ''Use of Tracers in Animal Food, Type A Medicated Articles, and Medicated Feeds.'' FDA's Center for Veterinary Medicine receives inquiries regarding the use of ''tracers'' in animal food, medicated feeds, and Type A medicated articles. Tracers are ingredients added to these products to identify a particular product. The purpose of this document is to provide guidance on the use of tracers in animal food, medicated feeds, and Type A medicated articles. When finalized, this guidance will replace CPG Sec. 680.100 Tracers in Animal Feed.

This level 1 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 the use of tracers in animal food, Type A medicated articles, and medicated feeds. 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 501.22 have been approved under OMB control number 0910–0721. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, 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. 2022–04370 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–2777]

Expansion Cohorts: Use in First-in-Human Clinical Trials 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 ''Expansion Cohorts: Use in First-in-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics.'' The purpose of this guidance is to provide advice to sponsors regarding the design and conduct of first-in-human (FIH) clinical trials intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs. This guidance finalizes the draft guidance of the same name issued in August 2018.

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–2777 for ''Expansion Cohorts: Use in First-in-Human Clinical Studies 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 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: Lee Pai-Scherf, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2314, Silver Spring, MD 20993–0002, 240–402–7911; 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 ''Expansion Cohorts: Use in First-in-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics.'' The purpose of this guidance is to provide advice to sponsors regarding the design and conduct of FIH clinical trials intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs. These are trial designs that employ multiple, concurrently accruing, subject cohorts, where individual cohorts assess different aspects of the safety, pharmacokinetics, and antitumor activity of the drug product. This guidance provides FDA's current thinking regarding (1) characteristics of drug products best suited for consideration for development under a multiple expansion cohort trial; (2) information to include in investigational new drug application submissions to support the use of individual cohorts; (3) when to interact with FDA on planning and conducting multiple expansion cohort trials; and (4) safeguards to protect subjects enrolled in FIH expansion cohort trials.

This guidance finalizes the draft guidance of the same name issued August 13, 2018 (83 FR 40055). Changes made to the guidance took into consideration public comments received. Major changes from the draft to the final guidance include the following:

- Language added stating that designs other than Simon two-stage (*e.g.,* Bayesian statistical design) may be used to assess antitumor activity in a nonrandomized cohort to limit the number of subjects that could be exposed to a potentially ineffective drug.
- Statement added to indicate that in trials of limited sample size, a safety assessment committee could be a group within the sponsor's organization alone that is not otherwise involved in trial conduct or management or with external representation in lieu of an independent data monitoring committee.
- Language added to state that development of an age-appropriate formulation may be necessary for pediatric populations.
- Minor changes added to various sections to clarify criteria for drug products suitable for investigation in clinical trials with FIH multiple expansion cohorts, the procedure for obtaining a risk assessment if an in vitro diagnostic will be used for patient management, and the information to be submitted to the FDA to support amendments to expand the protocol.

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 ''Expansion Cohorts: Use in First-in-Human Clinical Trials 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 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