DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Clinical Trial Design Considerations for Malaria Drug Development Media; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding clinical trial design considerations for malaria drug development. FDA is interested in discussing the scientific challenges pertaining to malaria drug development and malaria parasite detection methods used as endpoints in clinical trials. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. government agencies, public health organizations, academic experts, and industry on various aspects of the design of clinical trials evaluating new drugs to treat malaria. The input from this public workshop will also help in developing topics for future discussion.

Dates and Times: The public workshop will be held on June 30, 2016, from 8:30 a.m. to 4 p.m.

Location: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Bldg. 31 Great Rm., Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Ms. Lori Benner and/or Ms. Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 6221, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to *Malariaworkshop2016@fda.hhs.gov*. Persons without access to the Internet can call 301–796–1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Ms. Jessica Barnes or Ms. Lori Benner (see *Contact Persons*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific and regulatory considerations in the design of clinical trials of antimalarial drugs. Discussions will focus on developing two or more drugs used in combination, human challenge studies, issues/challenges associated with current detection methods, use of polymerase chain reaction, and other emerging rapid diagnostic tests in clinical trials.

The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857. Transcripts will also be available on the Internet at *http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm490084.htm?SSContributor=true* approximately 45 days after the workshop.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10913 Filed 5–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1210]

Technical Considerations for Additive Manufactured Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Technical Considerations for Additive Manufactured Devices.'' FDA has developed this draft leapfrog guidance to provide FDA's initial thoughts on technical considerations specific to devices using additive manufacturing, the broad category of manufacturing encompassing 3-dimensional (3D) printing. Specifically, this draft guidance outlines technical considerations associated with additive manufacturing processes, and testing and characterization for final finished devices fabricated using additive manufacturing. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 8, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of

Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–1210 for ''Technical Considerations for Additive Manufactured Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the draft guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Technical Considerations for Additive Manufactured Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or 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 request.

FOR FURTHER INFORMATION CONTACT: Matthew Di Prima, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2214, Silver Spring, MD 20993–0002, 301–796–2507; 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this draft leapfrog guidance to provide FDA's initial thoughts on technical considerations specific to devices using additive manufacturing (AM), the broad category of manufacturing encompassing 3D printing. In medical device applications, AM has the advantage of facilitating the creation of anatomically-matched devices and surgical instrumentation by using a patient's own medical imaging. Another advantage is the ease in fabricating complex geometric structures, allowing the creation of engineered open lattice structures, tortuous internal channels, and internal support structures that would not be easily possible using traditional (non-additive) manufacturing approaches. However, the unique aspects of the AM process, such as the layer-wise fabrication process, and the relative lack of medical device history of devices manufactured using AM techniques, pose challenges in determining optimal characterization and assessment methods for the final finished device, as well as optimal process validation and verification methods for these devices. To discuss these challenges and obtain initial stakeholder input, the FDA held a public workshop entitled ''Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3D Printing,'' on October 8–9, 2014 (*http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm397324.htm*). When finalized, this draft guidance document will recommend technical aspects of an additively manufactured device that should be considered through the phases of development, production process, process validation, and final finished device testing.

This draft guidance is a leapfrog guidance; leapfrog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development. This leapfrog guidance represents the Agency's initial thinking, and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with CDRH and/or CBER through the Pre-Submission process to obtain more detailed feedback regarding their AM device or process. For more information on Pre-Submissions, please see ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf*).

II. Significance of Guidance

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 technical considerations for additive manufactured devices. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/*

DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Technical Considerations for Additive Manufactured Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400002 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

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 collections of information in 21 CFR part 814, subparts B and E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: May 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10924 Filed 5–9–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

Proposed Project: Million Hearts Social Network Analysis: Network Survey—OMB No. 0990–New—Office of the Assistant Secretary for Planning and Evaluation (ASPE).

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting approval on a new information collection request from the Office of Management and Budget (OMB) for purposes of conducting a study about the Million Hearts Initiative and its subsequent public-private partner network.

Million Hearts focuses on aligning the efforts of federal agencies, states, regions, health systems, communities and individuals towards this common goal, ensuring the coordination of public health, clinical care, and policy approaches to this complex problem. Previous research has shown that collaborative efforts among organizations with a variety of programming, resources and skill sets result in higher levels of community impact. Integrated efforts to address public health issues by involving multiple stakeholders are predicted to result in better health outcomes than programs that do not use a collaborative approach.

ASPE is requesting comment on the burden for this study that is examining the Million Hearts public-private partnership network. The goal of developing this activity is to examine the network to identify facilitators and barriers to effective communication and collaboration in addressing large and complex public health problems like cardiovascular disease. This project wants to take the lessons learned from this unique and massive collaboration and apply them to other efforts to improve the health and well-being of Americans.

DATES: Comments on the ICR must be received on or before June 9, 2016.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title:

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Million Hearts Network Survey	100	1	30/60	50
Total				50

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2016–10953 Filed 5–9–16; 8:45 am]

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