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 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.

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.

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](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](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](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](http://www.regulations.gov) and insert the docket number, found in brackets in the heading, 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; 301–796–3507; 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](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/UCM311716.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311716.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/](http://www.fda.gov/MedicalDevices/)...
Darius Taylor, Information Collection Clearance Officer.

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 OHRA_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: Million Hearts Network Survey

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Million Hearts Network Survey</td>
<td>100</td>
<td>1</td>
<td>30/60</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>50</td>
</tr>
</tbody>
</table>

Dated: May 4, 2016.

Leslie Kux, Associate Commissioner for Policy.