DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6312]

Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public workshop entitled ''Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.'' The purpose of the public workshop is to convene a discussion on how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidance to the Agency. This workshop will inform development of patient-focused drug development guidance as required by the 21st Century Cures Act (Cures Act). FDA plans to publish a background document approximately 2 weeks before the workshop date.

DATES: The public workshop will be held on March 19, 2018, from 1 p.m. to 5 p.m. Submit either electronic or written comments on this public workshop by May 18, 2018. See the **SUPPLEMENTARY INFORMATION** section for additional registration information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), 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 *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*. Workshop updates, agenda, and background document will be made available at *https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm* prior to the workshop.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 18, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 18, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2017–N–6312 for ''Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 240–402–6525, Fax: 301–847–8443, *Meghana.Chalasani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop is intended to support FDA implementation of requirements for guidance development under section 3002 of the Cures Act (Pub. L. 114–255). Section 3002 of Title III, Subtitle A, of the Cures Act directs

FDA to develop patient-focused drug development guidance to address a number of areas, including how a person seeking to develop and submit a proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidances.

In FDA's ''Plan for Issuance of Patient-Focused Drug Development Guidance,'' (the Plan) available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM563618.pdf,* the Agency proposed issuing a guidance addressing this topic described in section 3002 during the second quarter of 2018. FDA recognizes that, like the other patient-focused drug development guidances described in the Plan, developing this draft guidance will also benefit from public input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders prior to FDA's drafting of the guidance. Accordingly, the Agency is scheduling this public workshop. After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket, and publish a draft guidance by the end of fiscal year 2018.

II. Purpose and Scope of Meeting

FDA is announcing a public workshop to convene a discussion on topics related to developing and submitting proposed draft guidance relating to patient experience data by an external stakeholder. The purpose of this public workshop is to obtain input from stakeholders on considerations for development and submission of proposed draft guidance relating to patient experience data submitted by an external stakeholder, including: (1) Defining the scope of the proposed draft guidance, (2) developing the proposed draft guidance, and (3) submitting the proposed draft guidance to FDA, including the process and format. The Agency is seeking information and comments from a broad range of stakeholders, including patients, patient advocates, academic and medical researchers, expert practitioners, drug developers, and other interested persons. FDA will publish a background document outlining the topic areas that will be addressed in the draft guidance approximately 2 weeks before the workshop date at the following website: *https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm.*

After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket, and publish a draft guidance by the end of fiscal year 2018.

III. Participating in the Public Workshop

Registration: Interested parties are encouraged to register early. To register electronically, please visit *https://pfdd-proposeddraftguidance.eventbrite.com.* Persons without access to the internet can call 240–402–6525 to register. If you are unable to attend the public workshop in person, you can register to view a live webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public workshop will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public workshop.

Open Public Comment: There will be time allotted during the public workshop for open public comment. Sign-up for this session will be on a first-come, first-serve basis on the day of the public workshop. Individuals and organizations with common interests are urged to consolidate or coordinate, and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: As soon as a transcript is available of the public workshop, FDA will post it at *https://www.fda.gov/Drugs/NewsEvents/ucm582081.htm.*

Dated: December 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26978 Filed 12–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Natalie Greco, 301–761–7898; *Natalie.Greco@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Monoclonal Antibody Specific for DNA/RNA Hybrid Molecules

Description of Technology

NIAID has a hybridoma available for non-exclusive licensing that produces a monoclonal antibody specific for DNA/RNA hybrids. This antibody, which has been extensively characterized by NIH researchers, is already a widely-used research tool. It is currently the only monoclonal antibody available that is specific for DNA/RNA hybrids, making it a unique reagent. It is used in immuno-fluorescence (IF) microscopy, where it can be used to detect sites of transcriptional activity and potentially sites of viral replication. It has also been used in DNA/RNA immunoprecipitation (DRIP) experiments by a variety of researchers.

Aside from its use as a research tool, this antibody has potential to be used in diagnostic kits for viral/bacterial infections, cancers, and a variety of other human diseases. DNA/RNA hybrids arise during normal cellular function, but they are typically present in cells at low levels. When DNA/RNA hybrids are found at high levels in a cell, it indicates that the cell is ''abnormal''. For example, the cell may be cancerous or infected with a virus. NIH researchers have also incorporated the antibody into a micro-array platform, expanding its potential for use in diagnostic devices.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.