

under OMB control number 0910–0733 is available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf>; 21 CFR parts 50 and 56 under OMB control number 0910–0755; the guidance for industry entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” under OMB control number 0910–0765 is available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>; and the ICH guidance for industry entitled “E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)” under OMB control number 0910–0843 is available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM464506.pdf>.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2455]

Patient-Focused Drug Development Guidance: Methods To Identify What is Important to Patients and Select, Develop, or Modify Fit-for-Purpose Clinical Outcome Assessments; 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) is announcing a 2-day public workshop to convene a discussion on methodological approaches that may be used to identify what is most important to patients and caregivers with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease, and best practices for selecting, developing, or modifying

fit-for-purpose clinical outcome assessments (COAs) to measure the patient experience in clinical trials. This workshop will inform development of patient-focused drug development guidance as required by the 21st Century Cures Act (Cures Act) and as part of commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). FDA will publish discussion documents approximately 1 month before the workshop date. FDA is interested in seeking information and comments on the approaches proposed in the discussion documents. FDA is also interested in input on examples, which could be illustrated in the draft guidance, where the approaches proposed in the discussion document have been successfully applied.

DATES: The public workshop will be held on October 15 and 16, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by December 14, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and 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 discussion documents will be made available at: <https://www.fda.gov/Drugs/NewsEvents/ucm607276.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 December 14, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 14, 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–2018–N–2455 for “Patient-Focused Drug Development Guidance: Methods to Identify What is Important to Patients and Select, Develop or Modify Fit-for-Purpose Clinical Outcome Assessments; Public Workshop; Request for Comments.” 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) and to meet a performance goal included in the sixth authorization of PDUFA VI. 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 methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease; and approaches to identifying and developing methods to measure impacts to patients that will help facilitate

collection of patient experience data in clinical trials.

In addition, FDA committed to meet certain performance goals under PDUFA VI. This reauthorization, part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017, includes a number of performance goals and procedures that are documented in the PDUFA VI Commitment Letter, which is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section J.1 of the commitment letter, “Enhancing the Incorporation of the Patient’s Voice in Drug Development and Decision-Making,” (<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

Prior to the issuance of each guidance, as part of the development, FDA will conduct a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders.

II. Purpose and Scope of Meeting

FDA is announcing a 2-day public workshop to convene a discussion on: (1) Methodological approaches that may be used to develop and identify what is most important to patients and caregivers with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease and (2) best practices for selecting, developing, or modifying fit-for-purpose COAs to measure the patient experience in clinical trials. The purpose of this public workshop is to obtain feedback from stakeholders on: (1) Methods to identify what is important to patients; (2) best practices for eliciting information on which aspects of disease symptoms, signs, impacts, and other issues are important and meaningful to patients; (3) measuring symptoms, signs, impacts and other issues of a disease or condition in a meaningful way; and (4) selecting, developing, or modifying fit-for-purpose COAs to measure the

patient experience in clinical trials. FDA 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 discussion documents outlining the topic areas that will be addressed in the draft guidances. These documents will be published approximately 1 month before the workshop date on the website at: <https://www.fda.gov/Drugs/NewsEvents/ucm607276.htm>. FDA is interested in seeking information and comments on the approaches and considerations proposed in the discussion documents. FDA is also interested in seeking information and comments on additional examples, which could be included in guidance, where the approaches proposed in the discussion document have been successfully applied. After this public workshop, FDA will take into consideration the stakeholder input from the workshop and the public docket and publish draft guidance(s).

III. Participating in the Public Workshop

Registration: Interested parties are encouraged to register early. To register electronically, please visit: <https://pfddmethods.eventbrite.com>. Registration for in-person attendance will close on October 10, 2018. Registration for the webcast will remain open until the day of the meeting. Persons without access to the internet can call 240-402-6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. 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 meeting 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 meeting.

Request for Oral Presentations: There will be time allotted during the workshop for open public comment. Sign-up for this session will be on a first-come, first-served basis on the day of the 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, FDA will post it at <https://www.fda.gov/Drugs/NewsEvents/ucm607276.htm>.

Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3009]

Authorization of Emergency Use of a Freeze Dried Plasma Treatment for Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for a freeze dried plasma treatment for hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by the U.S. Department of Defense (DoD). The Authorization contains, among other things, conditions on the emergency use of the authorized treatment. The Authorization follows the June 7, 2018, determination by the Deputy Secretary of Defense that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. The Deputy Secretary of Defense further stated that, more specifically, U.S. forces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause

major and imminently life-threatening combat casualties involving uncontrolled hemorrhage. On the basis of such determination, the Department of Health and Human Services (HHS) Secretary declared on July 9, 2018, that circumstances exist justifying the authorization of emergency use of freeze dried plasma for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of July 9, 2018.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT:

Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276), the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), 21st Century Cures Act (Pub. L. 114-255), and Public Law 115-92 (2017), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be

used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents and other agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;¹ (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section

¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine, within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.