II. Significance of Guidance

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 ''Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes.'' 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 guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Clinical Considerations for Investigational Device Exemptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500021 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; and the collections of information in the guidance document entitled ''Request for Feedback on Medical Device Submissions: The Pre-submission Program and Meetings With Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: November 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26783 Filed 11–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3462]

Establishment of the Patient and Care-Partner Connection; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to receive input on the Center for Devices and Radiological Health's (CDRH) new program, entitled the Patient and Care-partner Connection (P&CC). P&CC will partner with patient organizations to provide a means for CDRH staff to formally engage with patients and care-partners. The purpose of this partnership is to gain perspective and feedback from patients, care-partners, and patient organizations on particular topics of interest, such as, the scope and nature of P&CC and how to partner with patient organizations. The Agency is interested in facilitating staff engagement with patients and care-partners regarding specific disease states and/or medical devices used for treatment, diagnosis, or assessment.

DATES: Submit either electronic or written comments by January 6, 2017.

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–N–3462 for ''Establishment of the Patient and Care-partner Connection; Establishment of a Public Docket; Request for Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Anne Hammer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5400, Silver Spring, MD 20993, 301–796–4642, FAX: 301–847–8510, *anne.hammer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

One of the three CDRH 2016–2017 Strategic Priorities is to ''Partner with Patients'' [1] (Ref. 1). This priority reflects and builds on our strong commitment to patients, who are our most important customers. CDRH believes that to successfully achieve this mission, we must consider and engage with patients as partners. With regard to this priority, CDRH also understands that family or care-partners are integral to patient care and management of disease, and we are also committed to engaging them in order to fulfill this mission. FDA will work with both groups to advance the development and evaluation of innovative medical devices and to monitor the performance of marketed devices. In addition, partnerships will be leveraged, by promoting a culture of meaningful patient engagement and interaction between CDRH staff and patients and care-partners.

To achieve this goal, FDA intends to establish a new program, called the Patient and Care-partner Connection (P&CC). This program is designed to provide CDRH staff with a formal process by which they can engage with patients and care-partners to obtain input on key issues. P&CC will broaden CDRH's exposure to patients' and care-partners' experiences regarding specific disease states and/or medical devices used for the patient's treatment, diagnosis, or assessment. It will not solicit or provide external policy advice or opinion.

Additionally, P&CC will provide an avenue for designated groups of patients and care-partners to address specific questions pertinent to their treatment, diagnosis, or assessment by partnering with patient organizations in an effort to connect their members with CDRH staff, when the need for input arises. Patient organizations shall be 501(c)(3) organizations that have infrastructure conducive to soliciting patient and caregiver participation, and whose membership possesses relevant experience. Topics will be highly focused and restricted to specified disease states and/or medical devices.

Patients and care-partners will participate in P&CC on a gratuitous basis. Patients and care-partners will also report any conflict of interests they may have that are pertinent to the discussion, although conflicts of interest may not disqualify a patient or care-partner from participating in P&CC.

II. Patient and Care-Partner Connection Program

The Agency is seeking comments from interested persons on P&CC in general, and on the following questions:

General

- What are potential barriers to inclusion for patients and care-partners?
- What can FDA do to avoid or remedy any barriers to inclusion?
- What might patients and care-partners see as appropriate and effective engagement with FDA?
- How appropriate is the program title, ''Patient and Care-partner Connection''?
- What, if any, other titles should FDA consider?

Inclusion

- What types of organizations are appropriate for such a partnership?
- What are potential barriers to effective communication between FDA, partner organizations, patients, and care-partners?
- How can FDA engage patients, especially those who are hard to reach or from underserved communities who are typically underrepresented in such initiatives?

Communication

- What lines of questioning would be considered appropriate?
- What characteristics of such a program might patients and care-partners view especially positively and/or negatively?
- What methods or qualities of communication might be preferred or convenient for patients and care-partners?

III. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov*. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, Center for Devices and Radiological Health, ''2016–2017 Strategic Priorities,'' available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf*.

Dated: October 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26784 Filed 11–4–16; 8:45 am]

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[1] CDRH's 2016–2017 Strategic Priorities, in addition to ''partner[ing] with patients,'' include ''Establish a National Evaluation System for Medical Devices'' and ''Promote a Culture of Quality and Organizational Excellence.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0868]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on establishing notification of a consignee and consignee notification of a recipient's