''Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This guidance provides recommendations on the general principles to consider when drafting an indication and how to write, organize, and format the information in the Indications and Usage section of the labeling. The draft guidance provides recommendations on what information to include in the indication and when limitations of use should be considered for the Indications and Usage section.

The Indications and Usage section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.[1] The draft guidance describes how to clearly convey such information and addresses circumstances where other information in addition to the identification of the disease or condition may be warranted.

The draft guidance describes circumstances in which an indication may be broader than the specific parameters of the clinical studies supporting approval, as well as those where a narrower indication may be appropriate, and explains that the Indications and Usage section needs to make clear the scope of the indication. The draft guidance also describes circumstances in which an indication in an age group broader than the population that was studied may be considered for an adult population. However, this approach is generally not appropriate across pediatric populations or between adult and pediatric populations because of the statutory requirements related to pediatric assessments and the unique clinical considerations for pediatric patients. For example, pediatric patients may metabolize drugs differently from adults (in an age-related manner), are susceptible to different safety risks, and often require different dosing regimens, even after correction for weight. For these reasons, FDA recommends that age groups should be included in indications. An indication should state that a drug is approved, for example, ''in adults,'' ''in pediatric patients X years of age and older,'' or ''in adults and pediatric patients X years of age and older.'' FDA is interested in obtaining information and public comment on this recommendation and the implications of routinely including age groups in indications.

[1] See 21 CFR 201.57(c)(2).

This guidance is one in a series of guidances FDA is developing or has developed to assist applicants with the content and format of labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and additional guidances on labeling can be accessed at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm.* The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

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 the content and format of the Indications and Usage section of labeling for human prescription drug and biological products. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft 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 201.56 and 201.57 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR 312.41 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 314.126(c) and 314.70 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338.

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/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: June 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14535 Filed 7–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0545]

Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry.'' The guidance document provides blood establishments that collect Whole Blood and blood components with revised recommendations to reduce the risk of transmission of Zika virus (ZIKV) by blood and blood components. The guidance does not apply to the collection of Source Plasma. The guidance announced in this notice supersedes the document of the same title dated August 2016 (August 2016 Guidance).

DATES: The announcement of the guidance is published in the **Federal Register** on July 9, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2016–D–0545 for ''Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry.'' The guidance provides blood establishments that collect Whole Blood and blood components with revised recommendations to reduce the risk of transmission of ZIKV by blood and blood components. The guidance does not apply to the collection of Source Plasma. This guidance supersedes the August 2016 Guidance.

In the August 2016 Guidance, FDA recognized ZIKV as a relevant transfusion-transmitted infection under 21 CFR 630.3(h) and recommended universal individual donation nucleic acid testing (ID NAT) for ZIKV or the use of an FDA-approved pathogen reduction device. Since 2016, the number of ZIKV disease cases in the U.S. States and territories has decreased considerably. In addition, FDA has licensed a nucleic acid screening test(s) for the detection of ZIKV in individual or pooled samples. Considering the changing epidemiology of ZIKV in the United States and the availability of licensed screening tests, FDA is revising the recommendations contained in the August 2016 Guidance. In this guidance FDA explains that, in order to comply with the testing requirements in 21 CFR 610.40(a)(3), blood establishments must test all donations collected in the United States and its territories with a licensed nucleic acid test for ZIKV, using either ID NAT or minipool (MP) NAT. The guidance explains the basis for FDA's determination that universal MP NAT screening, with certain conditions identified to trigger ID NAT when local mosquito-borne ZIKV transmission is presumed in a collection area, provides an adequate and appropriate safeguard against the current and future risk of ZIKV transmission through blood transfusion. Alternatively, blood establishments can use an FDA-approved pathogen reduction device. The revised recommendations are less burdensome for blood establishments because fewer tests will be performed when donations are tested by MP NAT compared to ID NAT. However, the recommendations are consistent with public health considering the changing course of the ZIKV epidemic in the United States and the sensitivity of the licensed test(s) to detect ZIKV in blood donation.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate. Specifically, we are not seeking comments because the guidance presents a less burdensome policy for reducing the risk of transfusion-transmitted ZIKV that is consistent with public health. The guidance represents the current thinking of FDA on recommendations for reducing the risk of Zika virus transmission by blood and blood components. 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. This guidance is not subject to Executive Order 12866.

II. 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 parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14537 Filed 7–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Pregnancy in Women with Disabilities.

Date: July 23, 2018.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Networks and Behavior in Psychiatric Disorders.

Date: July 25, 2018.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR17–158: Epigenomes and Connectomes in Psychiatric Disorders.

Date: July 26, 2018.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 3, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–14647 Filed 7–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Environmental Determinants of Diabetes.

Date: July 9, 2018.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7351, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–8886, *sanoviche@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Review of Planning Grant Application (U34).

Date: July 12, 2018.

Time: 6:00 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK U34 Telephone Review.

Date: July 13, 2018.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, g*uox@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing