substantial equivalence to a legally marketed predicate device.

In the **Federal Register** of January 7, 2014 (79 FR 829), the Agency issued the draft guidance entitled ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' In the **Federal Register** of April 9, 2014 (79 FR 19622), the Agency announced that the deadline for the comment period would be extended until May 7, 2014, to allow for more public comments on this draft guidance document. FDA considered the comments received on this draft guidance and FDA revised the guidance as appropriate in response to the comments.

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 ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.'' 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 ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1756 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 and guidance. 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 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in the guidance document ''Requests 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: October 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24431 Filed 10–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1445]

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' This document describes studies and criteria that FDA recommends be used when submitting premarket notifications (510(k)s) for blood glucose monitoring systems (BGMSs) which are for prescription point-of-care use in professional healthcare settings. FDA intends for this document to serve as a guide for manufacturers in conducting appropriate performance studies and preparing 510(k)s for these device types.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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–2013–D–1445 for ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use; Guidance for Industry and Food and Drug Administration Staff; Availability.'' 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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single copy of the guidance document to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Leslie Landree, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4623, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6147.

SUPPLEMENTARY INFORMATION:

I. Background

This document describes studies and criteria that FDA recommends be used when submitting 510(k)s for BGMSs which are for prescription point-of-care use in professional settings. FDA intends for this document to serve as a guide for manufacturers in conducting appropriate performance studies and preparing 510(k)s for these device types. This document is not meant to address self-monitoring blood glucose test systems (SMBGs) for over-the-counter (OTC) home use by lay-users. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance ''Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use'' to address those device types.

Historically, FDA has not recommended different types of information in 510(k)s for BGMSs used by healthcare professionals as compared to SMBGs intended for home use by lay-users. However, it has become increasingly clear that these different use settings have distinct intended use populations with unique characteristics that can impact device design specifications, and that manufacturers should take these unique characteristics into account when designing their devices. In order to distinguish between FDA recommendations for prescription-use blood glucose meters, which are intended for use in point-of-care professional healthcare settings, and SMBG devices intended for home use for self-monitoring by lay-persons, the Agency is issuing two separate guidances for (i) BGMSs intended for use in point-of-care professional healthcare settings, and (ii) SMBGs intended for home use for self-monitoring by lay-users. FDA believes that in making this distinction, BGMSs can be better designed to meet the needs of their intended use populations, thereby providing greater safety and efficacy.

Because BGMSs are used in professional healthcare settings, they are more likely to be used on multiple patients. The Centers for Medicare and Medicaid Services and Centers for Disease Control and Prevention have expressed concern over the possibility that blood glucose meters can transmit bloodborne pathogens if these devices are contaminated with blood specimens and shared between users without effective cleaning, disinfecting, and appropriate infection control measures. This document describes certain design features and capacity for cleaning and disinfection to prevent the spread of bloodborne pathogens.

In addition, concerns have been raised citing the inability of currently cleared BGMSs to perform effectively in professional healthcare settings because these devices have not been adequately evaluated in some of the populations in which they are being used. Patients in professional healthcare settings are often fundamentally different than lay-users using these devices at home. Patients in professional healthcare settings can be acutely ill and medically fragile and are more likely to present physiological and pathological factors that could interfere with glucose measurements relative to lay-users. Errors in BGMSs accuracy can lead to incorrect insulin dosing, which, when combined with other factors, can lead to increased episodes of hypoglycemia. For hospitalized patients who may be seriously ill, glucose meter inaccuracies could further increase risk to health. This document describes studies that can be conducted to demonstrate BGMS performance for devices intended to be used in diverse professional healthcare settings on subjects in various states of health. While FDA recommends that the information described in this guidance be included in premarket submissions for BGMSs, submissions containing alternative information may be sufficient if able to demonstrate substantial equivalence to a legally marketed predicate device.

In the **Federal Register** of January 7, 2014 (79 FR 830), the Agency issued the draft guidance entitled ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use''. In the **Federal Register** of April 9, 2014 (79 FR 19622), the Agency announced that the deadline for the comment period would be extended until May 7, 2014, to allow for more public comments on this draft guidance document. FDA considered the comments received on this draft guidance and FDA revised the guidance as appropriate in response to the comments.

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 ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.'' 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 ''Blood Glucose Monitoring Test Systems for Prescription Point-of-Care

Use'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1755 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 and guidance. 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 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in the guidance document ''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' have been approved under OMB control number 0910–0598; and the collections of information in the guidance document ''Requests 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: October 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24430 Filed 10–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health (NIMH); Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to discuss business, agency updates, and issues related to autism spectrum disorder (ASD) research and services activities. The Committee will discuss the 2016–2017 update of the IACC Strategic Plan. The meeting will be open to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting.

Date: October 26, 2016.

Time: 9:00 a.m. to 5:00 p.m.* Eastern Time * Approximate end time.

Agenda: To discuss business, updates, and issues related to ASD research and services activities. The Committee will discuss updates of the IACC Strategic Plan.

Place: National Institutes of Health , 31 Center Drive, Building 31, C Wing, 6th Floor, Conference Room 6, Bethesda, MD 20892.

Webcast Live: https://videocast.nih.gov.

Conference Call Access: Dial: 888–469–2037, Access code: 3353029.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC Web site (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. Onsite registration will also be available.

Deadlines: Notification of intent to present oral comments: Wednesday, October 12, 2016 by 5:00 p.m. ET.

Submission of written/electronic statement for oral comments: Tuesday, October 18, 2016 by 5:00 p.m. ET.

Submission of written comments: Tuesday, October 18, 2016 by 5:00 p.m. ET.

For IACC Public Comment guidelines please see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/.*

Access: Medical Center Metro Station (Red Line).

Contact Person: Ms. Angelice Mitrakas, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892–9669, Phone: 301–435–9269, Email: *IACCPublicInquiries@mail.nih.gov.*

Public Comments: Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Wednesday, October 12, 2016, with their request to present oral comments at the meeting, and a written/electronic copy of the oral presentation/statement must be submitted by 5:00 p.m. ET on Tuesday, October 18,

A limited number of slots for oral comment are available, and in order to ensure that as many different individuals are able to present throughout the year as possible, any given individual only will be permitted to present oral comments once per calendar year (2016). Only one representative of an organization will be allowed to present oral comments in any given meeting; other representatives of the same group may provide written comments. If the oral comment session is full, individuals who could not be accommodated are welcome to provide written comments instead. Comments to be read or presented in the meeting must not exceed 250 words or 3 minutes, but a longer version may be submitted in writing for the record. Commenters going beyond the 250 word or 3 minute time limit in the meeting may be asked to conclude immediately in order to allow other comments and presentations to proceed on schedule.

Any interested person may submit written public comments to the IACC prior to the meeting by emailing the comments to *IACCPublicInquiries@mail.nih.gov* or by submitting comments at the web link: *https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp* by 5:00 p.m. ET on Tuesday, October 18, 2016. The comments should include the name, address, telephone number, and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. ET on Tuesday, October 18, 2016 will be presented to the Committee prior to the meeting for the Committee's consideration. Any written comments received after the 5:00 p.m. ET, October 18, 2016 deadline through October 25, 2016 will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided.

In the 2009 IACC Strategic Plan, the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.