

appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to conduct monitoring of clinical investigations and are, therefore, compatible with a range of approaches to monitoring.

Accordingly, we developed the guidance document entitled, "Guidance for Industry—Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring." The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug

and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors or by contract research organizations (CROs) that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. Finally, the guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Information collections for reports and records associated with clinical investigations under parts 312 and 812 are currently approved under OMB control numbers 0910-0014 and 0910-0078 respectively. These reporting and

recordkeeping provisions cover general elements. The guidance discusses other elements sponsors and investigators should consider and include in developing a monitoring plan. As explained in the guidance, documentation of monitoring should include sufficient detail to allow verification that the monitoring plan was followed. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both) regarding potential issues identified through monitoring should review the monitoring plan.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| Activity | Number of recordkeepers | Number of records per recordkeeper | Total Annual Records | Average burden per recordkeeping | Total hours |
|---|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| Documentation included in comprehensive monitoring plan | 88 | 1.5 | 132 | 4 | 528 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we have made no adjustments to our burden estimate. We estimate 88 sponsors will develop 132 comprehensive monitoring plans in accordance with the guidance. We believe the associated burden for each plan is approximately 4 hours and includes the time necessary to develop, and amend as appropriate, the monitoring plan.

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-26032 Filed 11-29-18; 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; Draft 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 draft guidance for industry and FDA staff entitled "Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use." This draft guidance document describes studies and criteria that FDA recommends be used when submitting premarket notifications (510(k)s) for blood glucose monitoring systems (BGMSs) that are for prescription point-of-care use. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by February 28, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2013–D–1445 for “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.” 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)).

An electronic copy of the draft guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use” 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, 10903 New Hampshire Ave., Bldg. 66, Rm. 4623, Silver Spring, MD 20993–0002, 301–796–6147.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2016, FDA published a final guidance entitled, “Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use.” That guidance document described studies and information that FDA recommends be used when submitting 510(k)s for BGMSs that are for prescription point-of-care use. FDA is now proposing to make modifications to the guidance based on feedback received from stakeholders, which the Agency believes will better align with the evolving understanding and development of these types of devices. When finalized, this draft guidance will replace the final

guidance of the same title issued on October 11, 2016.

II. Significance of Guidance

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 “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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This draft guidance document is also available at <https://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 GUD 1755 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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 the following FDA guidances and regulations have been approved by OMB as listed in the following table:

| 21 CFR part or guidance | Topic | OMB Control No. |
|--|--|-------------------------------------|
| 807, subpart E “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”. | Premarket Notification Q-Submissions | 0910–0120 0910–0756 |
| 800, 801, and 809 820 | Medical Device Labeling Regulations Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation. CLIA Waiver Applications | 0910–0485 0910–0073 0910–0598 |
| Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff. | | |

| 21 CFR part or guidance | Topic | OMB Control No. |
|---|--|-----------------|
| Administrative Procedures for CLIA Categorization—Guidance for Industry and Food and Drug Administration Staff. | Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization (42 CFR 493.17). | 0910–0607 |

Dated: November 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26034 Filed 11–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4116]

Bone, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on January 16, 2019, from 8:15 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–4116. The docket will close on January 14, 2019. Submit either electronic or written comments on this public meeting by January 14, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until

11:59 p.m. Eastern Time at the end of January 14, 2019. 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.

Comments received on or before December 31, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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–2018–N–4116 for “Bone, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; 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.” FDA 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 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 the 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