meetings designed to enhance harmonization, and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; FDA; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidance.

In the **Federal Register** of September 29, 2015 (80 FR 58492), FDA published a notice announcing the availability of a draft guidance entitled ''E6(R2) Good Clinical Practice.'' The notice gave interested persons an opportunity to submit comments on the ''ADDENDUM'' text added to ICH E6(R1) by November 30, 2015.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2016.

The guidance discusses approaches to clinical trial design, conduct, oversight, recording, and reporting as well as updated standards regarding electronic records and essential documents. This guidance includes additions to ICH E6(R1) that are identified as ''ADDENDUM'' and are marked with vertical lines on both sides of the text. The additions to ICH E6(R1) are intended to encourage implementation of the described approaches and processes to improve clinical trial quality and efficiency while maintaining human subject protection and reliability of trial results. Evolutions in technology and risk management processes offer new opportunities to increase clinical trial efficiency, in part by focusing on trial activities essential to ensuring human subject protection and the reliability of trial results. For example, the guidance recommends sponsors implement a system to manage quality throughout clinical trials and recommends sponsors develop a systematic, prioritized, risk-based approach to monitoring clinical trials. The guidance provides additional detail regarding recommendations for use of electronic records and essential documents. The final guidance includes clarifications and additional detail on topics including, for example, validation of computerized systems and centralized monitoring.

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 ''E6(R2) Good Clinical Practice: Integrated Addendum to E6(R1).'' 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.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (21 U.S.C. 3501–3520). The collections of information in this guidance were approved under 0910–0843. This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information found in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information found in 21 CFR part 56 have been approved under OMB control numbers 0910–0755; the collections of information found in 21 CFR part 312 have been approved under OMB control numbers 0910–0014 and 0910–0733; the collections of information found in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information found in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: February 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04154 Filed 2–28–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5925]

Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive Web Page; Reopening of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening a docket for public comment on the susceptibility test interpretive criteria for antibacterial and antifungal drugs provided by FDA on its Susceptibility Test Interpretive Criteria web page (Interpretive Criteria web page) established on December 13, 2017. On the Interpretive Criteria web page, FDA recognizes, in whole or in part, susceptibility test interpretive criteria standards established by Standard Development Organizations (SDOs) and lists other susceptibility test interpretive criteria identified by FDA outside of the SDO process.

DATES: This notice is published in the **Federal Register** on March 1, 2018.

ADDRESSES: You may submit either electronic or written comments and information 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–2017–N–5925 for ''Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive web page; Request for Comments.'' 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 to the docket at any time.

FOR FURTHER INFORMATION CONTACT: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182, *Katherine.Schumann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 13, 2017, FDA established the Interpretive Criteria web page (*https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm*) that contains a list of FDA-recognized susceptibility test interpretive criteria standards, established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360a–2(b)(2)(A)); identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria standards recognized by FDA on the Interpretive Criteria web page are deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)).

At least every 6 months after the establishment of the Interpretive Criteria web page, FDA will publish on the Interpretive Criteria web page a notice recognizing new or updated susceptibility test interpretive criteria standards, or parts of standards; withdrawing recognition of susceptibility test interpretive criteria standards, or parts of standards; and making any other necessary updates to the lists published on the Interpretive Criteria web page. Once a year FDA will compile the notices from that year and publish them in the **Federal Register** and provide for public comment. If comments are received, FDA will review those comments and make any updates to the recognized standards or susceptibility test interpretive criteria as needed.

II. Recommendation of New or Updated Susceptibility Test Interpretive Criteria for Listing by FDA

This **Federal Register** notice is a request for comments by interested third parties on FDA's initial susceptibility test interpretive criteria recognition and listing determinations on the Interpretive Criteria web page. FDA may consider information provided by interested third parties as a basis for updating interpretive criteria standards. This notice allows interested third parties the opportunity to comment on FDA's recognition and listing determinations before the annual compilation of notices of susceptibility test interpretive criteria changes made that year.

Interested third parties or drug sponsors may provide information that FDA could use as a basis for listing new or for updating susceptibility interpretive criteria. This information should be submitted to Docket No. FDA–2017–N–5925. If comments are received, FDA will review those comments and will make, as necessary, updates to the recognized standards or susceptibility test interpretive criteria.

If preferred, application holders may submit data supporting changes to FDA's susceptibility test interpretive criteria recognition or listing determinations through the application holder's annual report under the new drug application. If submitting this data, application holders are encouraged to identify in the cover letter of the annual report that the enclosed submission includes data supporting changes to FDA's susceptibility test interpretive criteria recognition or listing determinations. FDA will review these annual report submissions and

determine whether changes or updates to the currently recognized susceptibility test interpretive criteria are appropriate. FDA will then update the Interpretive Criteria web page to reflect these changes, as needed.

Dated: February 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04175 Filed 2–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0627]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 29 and 30, 2018, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg; Salons A, B, C, and D; 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. 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.*

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, *patricio.garcia@fda.hhs.gov;* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On March 29, 2018, the committee will discuss, make recommendations, and vote on information regarding a premarket approval application to market a novel continuous glucose monitoring (CGM) device system, the Senseonics, Inc. Eversense CGM System. This device requires minor surgery to implant and remove, and if approved, would provide 90 days of sensor glucose values from each implanted sensor.

The Eversense CGM System measures patients' glucose concentrations from subcutaneous interstitial fluid similar to approved CGM systems. All CGM devices currently or previously marketed used electrochemistry to measure glucose in interstitial fluids, last for 3 to 11 days and are inserted via a small-gauge needle by the end user. The proposed CGM system uses a fluorescence-based measurement technique, requires minor surgery for subcutaneous implantation, and will have a 90-day sensor wear period. The proposed CGM sensor also includes a drug component (dexamethasone acetate) intended to mitigate negative effects on sensor accuracy and sensor life from the foreign body response at the sensor insertion site. The proposed intended use, as stated by the sponsor, is as follows:

The Eversense CGM System continually measures glucose levels in adults (age 18 and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Aid in the management of diabetes.
- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time.

On March 30, 2018, the committee will discuss and make recommendations regarding measuring blood glucose using capillary blood with blood glucose meters in all hospital patients, including those receiving intensive medical intervention/therapy and patients with decreased peripheral blood flow, such as with severe hypotension, shock, hyperosmolar-hyperglycemia and severe dehydration (*e.g.,* patients in intensive care settings). Currently, FDA has cleared one glucose meter for use all over the hospital using venous and arterial blood. FDA understands that being able to make capillary blood measurements in all hospitalized patients using FDA cleared and Clinical Laboratory Improvement Amendments (CLIA) waived (*i.e.,* designated as waived per the standards in the CLIA) glucose meters would be more convenient and timely for hospital staff. FDA would like to present new data from capillary blood measurements on glucose meters in patients receiving intensive medical intervention/therapy to the Clinical Chemistry and Clinical Toxicology Devices Panel. FDA would like to receive feedback from the advisory panel on the benefits and risks of measuring capillary blood using blood glucose meters in this intended use population, and the considerations for CLIA waiver for this use.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 22, 2018. Oral presentations from the public will be scheduled on March 29 and 30, 2018, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 14, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled