issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''Clinical Decision Support Software'' to provide clarification of its interpretation of section 520(o)(1)(E) of the FD&C Act, which describes certain software functions intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of December 8, 2017 (82 FR 57991). FDA revised the guidance as appropriate in response to the comments. FDA has provided additional clarity that hardware intended to transfer, store, convert formats, and display medical device data and results remain devices, while software functions intended to transfer, store, convert formats, or display data are no longer devices if they meet the definition in 520(o)(1)(D) of the FD&C Act. The examples included in the draft of this guidance that described alarms, alerts, or flags have been removed from this guidance, because they are not excluded from the definition of device under section 520(o)(1)(D) of the FD&C Act in that these functions involve analysis or interpretation of laboratory test or other device data and results. These functions are addressed in section 520(o)(1)(E) of the FD&C Act, the regulation of which will be described in the separate ''Clinical Decision Support Software'' guidance document.

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 ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.'' 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 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17030 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subparts A through D	Establishment Registration And Device Listing	0910–0625
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21001 Filed 9–26–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6569]

Clinical Decision Support Software; 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 entitled ''Clinical Decision Support Software.'' This guidance clarifies the types of clinical decision support (CDS) functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures Act). This guidance describes a risk-based approach for regulatory oversight of CDS software functions that remain devices using the categories defined by the International Medical Device Regulators Forum (IMDRF) final document entitled ''Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations.'' The guidance also provides clarity on the types of CDS software functions on which FDA intends to focus its regulatory oversight for health care providers, patients, and caregivers. 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 December 26, 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–2017–D–6569 for ''Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff.'' 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 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 hard copy of the draft guidance document entitled ''Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, 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; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; or Kristina Lauritsen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6162, Silver Spring, MD 20993–0002, 301–796–8936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has long regulated software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h)), including software that is intended to provide decision support to health care professionals, patients, or caregivers for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as CDS software). Section 3060(a) of the Cures Act, enacted on December 13, 2016 (Pub. L. 114–255), amended section 520 of the FD&C Act (21 U.S.C. 360j) to exclude certain medical software functions, including certain decision support software, from the definition of device under section 201(h) of the FD&C Act.

This draft guidance provides clarity on the types of CDS software functions that do not meet the device definition (Non Device CDS). This draft guidance also describes a risk-based approach for regulatory oversight of CDS software functions that meet the device definition (Device CDS) using categories established by the IMDRF final document entitled ''Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations.'' The purpose of this draft guidance is to identify the types of CDS software functions that: (1) Do not meet the definition of a device as amended by the Cures Act; (2) may meet the definition of a device but for which, at this time and based on our current understanding of the risk of these devices, FDA does not intend to enforce compliance with the applicable device requirements of the FD&C Act, including, but not limited to, premarket clearance and premarket approval requirements; and (3) meet the definition of a device and on which FDA intends to focus its regulatory oversight. This guidance also provides examples of device software functions that are not CDS and on which FDA intends to focus its regulatory oversight. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the final guidance entitled ''Changes to Existing Medical Software Policies Resulting From

Section 3060 of the 21st Century Cures Act'' to provide clarification of its interpretation of section 520(o)(1)(A)–(D) of the FD&C Act (21 U.S.C. 360j(o)(1)(A)–(D)), as added by the Cures Act, for certain medical software functions that are not medical devices, including software functions that are intended: (1) For administrative support of a health care facility, (2) for maintaining or encouraging a healthy lifestyle, (3) to serve as electronic patient records, or (4) for transferring, storing, converting formats, or displaying data. Section 520(o)(2) of the FD&C Act describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.

On December 8, 2017, FDA announced in the **Federal Register** a draft guidance entitled ''Clinical and Patient Decision Support Software'' (82 FR 57987). FDA is issuing a revised draft guidance, now entitled ''Clinical Decision Support Software,'' after considering comments received on the draft guidance that issued December 8, 2017. This draft guidance provides FDA's risk-based policy for Device CDS software functions in response to comments received.

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 ''Clinical Decision Support Software.'' 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*. This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*. Persons unable to download an electronic copy of ''Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400062 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 regulations, guidance, and form have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo Classification Process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
314	Applications for FDA Approval to Market a New Drug	0910–0001
601; Form FDA 356h	Biologics License; Application to Market a New Drug or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–21000 Filed 9–26–19; 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: Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

Date: October 24, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Methode Bacanamwo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, Bethesda, MD 20892, 301–827–7088, *methode.bacanamwo@nih.gov*.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: October 24–25, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Jonathan K. Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2190, MSC, 7850 Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov*.