Development, Center for Biologics Evaluation and Research, 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 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 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On December 13, 2016, the Cures Act was signed into law. Section 3060(a) of this legislation entitled ''Clarifying Medical Software Regulation'' amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 520(*o*) (21 U.S.C. 360j(*o*)), which describes software functions that are excluded from the definition of the term device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). In addition, section 520(*o*)(2) of the FD&C Act describes the regulation and assessment of a software product with multiple functions, including at least one device function and at least one software function that is not a device. In this draft guidance, FDA provides its current thinking on the regulation of products with multiple functions with at least one device function. Although section 520(*o*)(2) of the FD&C Act applies to the regulation of *software* products containing at least one device function and at least one non-device function, FDA believes the same principles apply to *all* multiple function products that contain at least one device function.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Multiple Function Device Products: Policy and Considerations.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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 guidance document is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Multiple Function Device Products: Policy and Considerations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17038 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 have been approved by OMB as follows:

The collections of information in this 21 CFR part or guidance document:	Regarding this topic:	Have been approved under OMB control No.:
803	Medical device reporting	0910–0437
807, subparts A–D	Registration and listing	0910–0625
807, subpart E	Premarket notification	0910–0120
812	Investigational device exemption	0910–0078
814, subparts A–E	Premarket approval applications	0910–0231
814, subpart H	Humanitarian use devices	0910–0332
820	Current good manufacturing practice and the quality system regulation.	0910–0073
601	Biologics license applications	0910–0338
''User Fees for 513(g) Requests for Information'' and ''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) requests	0910–0705
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions and presubmissions	0910–0756
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo requests	0910–0844

Dated: April 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08858 Filed 4–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0586]

Clinical Trial Imaging Endpoint Process Standards; 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 guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' This guidance assists sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. This guidance

focuses on imaging acquisition, display, archiving, and interpretation process standards that FDA regards as important when imaging is used to assess a trial's primary endpoint or a component of that endpoint. This guidance finalizes the draft guidance of the same name issued on March 5, 2015.

DATES: The announcement of the guidance is published in the **Federal Register** on April 27, 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–2011–D–0586 for ''Clinical Trial Imaging Endpoint Process Standards; 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Libero (Louis) Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5482, Silver Spring, MD 20993–0002, 301–796–1414; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clinical Trial Imaging Endpoint Process Standards.'' The purpose of this guidance is to assist sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. It focuses on imaging acquisition, display, archiving, and interpretation standards that FDA regards as important when imaging is used to assess the trial's primary endpoint or a component of that endpoint. The guidance describes the minimum standards a sponsor should use to help ensure that clinical trial imaging data are obtained in a manner that complies with a trial's protocol, maintains imaging data quality, and provides a verifiable record of the imaging process.

This guidance addresses the background considerations for determining the role of imaging in a clinical trial as well as the major considerations in the development of an imaging charter that describes the trial's imaging methods. The guidance specifically addresses the technical components of a charter's description of the image acquisition, image interpretation, and image data development methods. This guidance finalizes the draft guidance issued on March 5, 2015 (80 FR 11998). Changes made to the draft guidance took into consideration written and verbal comments received. In addition to editorial changes primarily for clarification, changes also included the following: clarifying the recommended role of a centralized image interpretation process and the quality control process; streamlining the description of the recommended approach to incidental findings and to discordant image interpretations; and

highlighting further the interrelationship between a clinical protocol and an imaging charter.

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 clinical trial imaging endpoint process standards. 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 guidance refers to previously approved collections of information that 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 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

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

Dated: April 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08903 Filed 4–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

DATES: Wednesday, May 9, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time (ET) and Thursday, May 10, 2018, from 9:30 a.m. to 1:00 p.m. ET.

ADDRESSES: The public may attend this meeting in person or via Webcast. While this meeting will be open to the public, advance registration is required. Please register online at *http://www.achdncmeetings.org/* by 12:00 p.m. ET on May 7, 2018.

The address for the meeting is 5600 Fishers Lane, Rockville, MD 20857. Non-U.S. citizens planning to attend in person will need to provide additional information to HRSA by Monday, April 30, 2018, 12 p.m. ET. To facilitate access to the building, please contact Ann Ferrero at the contact information listed below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Ms. Ferrero at least 10 days prior to the meeting.

The meeting will also be accessible via Webcast. Instructions on how to access the meeting via Webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACHDNC should contact Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301–443–3999; or (3) send an email to *AFerrero@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The ACHDNC provides advice and recommendations to the Secretary of HHS on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC's recommendations regarding inclusion of additional conditions and inherited disorders for screening are included in the Recommended Uniform Screening Panel (RUSP) following adoption by the Secretary. Conditions listed on the RUSP constitute part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered health plans and health insurance issuers are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for screenings included in the HRSA-supported comprehensive guidelines for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Agenda: The meeting agenda will include: (1) Presentations and discussion on risk assessment in newborn screening; (2) presentation of educational tools for communicating newborn screening results; (3) presentations from states working toward timeliness goals in newborn screening; (4) an update on the status of newborn screening pilot studies for Guanidinoacetate Methyltransferase (GAMT) deficiency; (5) updates from the Laboratory Standards and Procedures workgroup; (6) updates from the Follow-up and Treatment workgroup; (7) updates from the Education and Training workgroup; and (8) reviewing the process for assessing the public health impact of adding conditions to the RUSP.

There are no votes scheduled for this meeting. The final meeting agenda will be available two (2) days prior to the meeting on the Committee's website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Please note that agenda items and meeting times are subject to change as priorities dictate.

Public Participation: Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on May 3, 2018, at *http://www.achdncmeetings.org/.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–08853 Filed 4–26–18; 8:45 am]

BILLING CODE 4165–15–P