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single hard copy of the draft guidance document entitled “Technical
Performance Assessment of Digital Pathology Whole Slide Imaging Devices” 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.
Submit electronic comments on the draft guidance to http://
www.regulations.gov. Submit written comments to the Division of Dockets
Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.
1061, Rockville, MD 20852. Identify comments with the docket number
found in brackets in the heading of this document.
FOR FURTHER INFORMATION CONTACT:
Nicholas Anderson, Center for Devices and Radiological Health, Food and Drug
Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5570, Silver Spring,
MD 20993–0002, 301–796–4310; or Aldo Badano, Center for Devices and Radiological Health, Food and Drug
Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3116, Silver Spring,
MD 20993–0002, 301–796–2534.
SUPPLEMENTARY INFORMATION:
I. Background
Recent technological advances in
digital microscopy, in particular the
development of whole slide scanning
systems, have accelerated the adoption of
digital imaging in pathology, similar to
the digital transformation that
radiology departments have experienced
over the last decade. FDA regulates WSI
systems manufacturers to ensure that the
images produced for clinical
intended uses are safe and effective for
such purposes. Essential to the
regulation of these systems is the
understanding of the technical
performance of the components in the
imaging chain, from image acquisition
to image display and their effect on
pathologist’s diagnostic performance and
workflow.
This draft guidance provides industry
and Agency staff with recommendations
regarding the technical performance
assessment data that should be included
for regulatory evaluation of a WSI. This
document does not cover the clinical
submission data that may be necessary
to support approval or clearance. The
guidance provides our suggestions on
how to best characterize the technical
aspects that are relevant to WSI
performance for their intended use and
determine any possible limitations that
might affect their safety and
effectiveness.
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 Agency’s current thinking
on technical performance assessment of
digital pathology WSI devices. It does
not create or confer any rights for or on
any person and does not operate to bind
FDA or the public. An alternative
approach may be used if such approach
satisfies the requirements of the
applicable statute and regulations.
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
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 “Technical Performance Assessment
of Digital Pathology Whole Slide
Imaging Devices” may send an email
request to CDRH-Guidance@fda.hhs.gov
to receive an electronic copy of the
document. Please use the document
number 1400053 to identify the
guidance you are requesting.
IV. Paperwork Reduction Act of 1995
This draft guidance refers to
previously approved collections of
information found in FDA regulations.
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
part 814 have been approved under
OMB control number 0910–0231, and
the collections of information in 21 CFR
part 801 and 21 CFR 809.10 have been
approved under OMB control number
0910–0485.
V. Comments
Interested persons may submit either
electronic comments regarding this
document to http://www.regulations.gov
or written comments to the Division of
Dockets Management (see ADDRESSES).
It is only necessary to send one set of
comments. Identify comments with the
docket number found in brackets in the
heading of this document. Received
comments may be seen in the Division of
Dockets Management between 9 a.m.
and 4 p.m., Monday through Friday, and
will be posted to the docket at http://
www.regulations.gov.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–03843 Filed 2–24–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2015–N–0001]
Pediatric Ethics Subcommittee of the
Pediatric Advisory Committee; Notice of
Meeting
AGENCY: Food and Drug Administration,
HHS.
ACTION: Notice.
This notice announces a forthcoming
meeting of a public advisory committee
of the Food and Drug Administration
(FDA). The meeting will be open to the
public.
Name of Committee: Pediatric Ethics
Subcommittee of the Pediatric Advisory
Committee.
General Function of the Committee:
To provide advice and
recommendations to the Agency
regarding ethical protections for
children in FDA-regulated clinical
trials.
Date and Time: The meeting will be
held on Monday, March 23, 2015 from
8:30 a.m. to 4:30 p.m.
Location: Doubletree by Hilton Hotel,
8727 Colesville Rd., Silver Spring, MD
20910. Answers to commonly asked
questions, including information
regarding special accommodations due
to a disability, visitor parking, and
transportation, may be accessed at:
http://www.fda.gov/
AdvisoryCommittees/
AboutAdvisoryCommittees/
ucm408555.htm.
Contact Person: Walter Ellenberg,
Office of the Commissioner, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 32, rm. 5154,
Silver Spring, MD 20993, 301–796–
0885, email walter.ellenberg@
fda.hhs.gov, or FDA Advisory
Committee Information Line, 1–800–
Robotically-Assisted Surgical Devices: Challenges and Opportunities; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the public workshop entitled “Robotically-Assisted Surgical (RAS) Devices: Challenges and Opportunities.” FDA is holding this public workshop to obtain information on the current challenges and opportunities related to robotically-assisted surgical medical devices, which are classified as Class II medical devices. The purpose of this workshop is to obtain public feedback from a scientific, clinical, and regulatory considerations associated with RAS devices. Comments and suggestions generated through this workshop will facilitate further development of regulatory science for RAS technologies.

DATES AND TIMES: The public workshop will be held on July 27 and July 28, 2015, from 8 a.m. to 5 p.m.

LOCATION: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, The Great Room (Rm. 1503A), Silver Spring, MD 20993.

Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

CONTACT PERSON: Mark Trumbore, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301–796–5436, Mark.Trumbore@fda.hhs.gov.

REGISTRATION: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by July 17, 2015, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting/public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: Susan.Monahan@fda.hhs.gov no later than July 14, 2015.

To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Mark Trumbore to register (see Contact Person). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.