particular diagnosis, prognosis, and monitoring or risk assessment.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on content and format for abbreviated 510(k)s for early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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 ''Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization 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 1400030 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations.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, are currently approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 809.10 are currently approved under 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.*

Dated: September 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22973 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0031]

Draft Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft guidance document entitled ''Informed Consent Information Sheet.'' A notice of availability requesting comments on the draft guidance document appeared in the **Federal Register** of July 15, 2014. The Agency is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by October 27, 2014.

ADDRESSES: Submit electronic comments 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.

FOR FURTHER INFORMATION CONTACT: Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Building 32, Silver Spring, MD 20993, *marsha.melvin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2014 (79 FR 41291), FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance document entitled ''Informed Consent Information Sheet.''

The Agency has received a request for a 30-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA is reopening the comment period for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance on these important issues.

II. Request for 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.*

Dated: September 19, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22951 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–0327, FDA–2014–M–0434, FDA–2014–M–0552, FDA–2014–M–0553, FDA–2014–M–0690; FDA–2014–M–0691, FDA–2014–M–0692, FDA–2014–M–0726, FDA–2014–M–0727, FDA–2014–M–0866, and FDA–2014–M–0872]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and

effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act (21 U.S.C. 360e(g)). The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2014, through June 30, 2014. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2014, THROUGH JUNE 30, 2014

PMA No., Docket No.	Applicant	Trade name	Approval date
P130016, FDA–2014–M–0327.	Cochlear Americas	Nucleus® Hybrid™ L24 Cochlear Implant System	March 20, 2014.
P120020, FDA–2014–M–0434.	Abbott Vascular (IDEV Technologies, Inc.).	SUPERA® Peripheral Stent System	March 28, 2014.
P010015/S205, FDA–2014–M–0553.	Medtronic, Inc	Cardiac Resynchronization Therapy Pacemaker (CRT–P) Devices.	April 10, 2014.
P010031/S381, FDA–2014–M–0553.	Medtronic, Inc	Cardiac Resynchronization Therapy Defibrillator (CRT–D) Devices.	April 10, 2014.
P100020/S008, FDA–2014–M–0552.	Roche Molecular Systems, Inc	cobas® HPV Test	April 24, 2014.
P130008, FDA–2014–M–0690.	Inspire Medical Systems, Inc	Inspire Upper Airway Stimulation (UAS) system	April 30, 2014.
P110005, FDA–2014–M–0691.	IBSA Institut Biochimique SA	Gel-Syn™ Sinovial (Sodium Hyaluronate 0.8%)	May 9, 2014.
P110041, FDA–2014–M–0692.	Siemens Healthcare Diagnostics	ADVIA Centaur® HBsAgII, ADVIA Centaur® HBsAg Confirmatory and ADVIA Centaur® HBsAg Quality Control Material.	May 16, 2014.
P110027, FDA–2014–M–0726.	QIAGEN Manchester Ltd	therascreen® KRAS RGQ PCR Kit	May 23, 2014.
P100045, FDA–2014–M–0727.	CardioMEMS, Inc	CardioMEMS™ HF System	May 28, 2014.
P130027, FDA–2014–M–0866.	QIAGEN, Inc	artus® CMV RGQ MDx Kit	June 2, 2014.
P040024/S072, FDA–2014–M–0872.	Valeant Pharmaceuticals North America LLC/Medicis.	Restylane Silk Injectable Gel	June 13, 2014.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: September 23, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22987 Filed 9–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Ophthalmic Devices Panel of the Medical Devices 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: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 14, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington, DC North/Gaithersburg, Montgomery Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.