meeting registration is available at: *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2016.*

SUPPLEMENTARY INFORMATION: HHS announces OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS Tribal Consultations in Albuquerque, New Mexico, Arlington, Virginia, and Spokane, Washington, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in the 2015 OHS Tribal Consultations.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. Tribal Governments must submit the designee letter at least 3 days in advance of the Consultation Session to Angie Godfrey at *Angie.Godfrey@acf.hhs.gov.* Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 45 days of the Consultation Sessions to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Angie Godfrey at *Angie.Godfrey@acf.hhs.gov* either prior to each Consultation Session or within 30 days after each meeting. OHS will summarize oral testimony and comments from the Consultation Session in each report without attribution, along with topics of concern and recommendations.

Dated: February 2, 2016.

Blanca E. Enriquez,

Director, Office of Head Start.

[FR Doc. 2016–02580 Filed 2–8–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–3256, FDA–2015–M–3257, FDA–2015–M–3258, FDA–2015–M–3376, FDA–2015–M–3377, FDA–2015–M–3516, FDA–2015–M–3516, FDA–2015–M–3519, FDA–2015–M–3520, FDA–2015–M–3521, FDA–2015–M–4013, FDA–2015–M–4014, FDA–2015–M–4015, FDA–2015–M–4016, FDA–2015–M–4017, FDA–2015–M–4018, FDA–2015–M–4069, FDA–2015–M–4343, FDA–2015–M–4344, FDA–2015–M–4434, FDA–2015–M–4728, FDA–2015–M–4947, and FDA–2015–M–4951]

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: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 Nos. FDA–2015–M–3256, FDA–2015–M–3257, FDA–2015–M–3258, FDA–2015–M–3376, FDA–2015–M–3377, FDA–2015–M–3516, FDA–2015–M–3516, FDA–2015–M–3519, FDA–2015–M–3520, FDA–2015–M–3521, FDA–2015–M–4013, FDA–2015–M–4014, FDA–2015–M–4015, FDA–2015–M–4016, FDA–2015–M–4017, FDA–2015–M–4018, FDA–2015–M–4069, FDA–2015–M–4343, FDA–2015–M–4344, FDA–2015–M–4434, FDA–2015–M–4728, FDA–2015–M–4947, and FDA–2015–M–4951 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524.

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. 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 October 1, 2015, through December 31, 2015. 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 OCTOBER 1, 2015, THROUGH DECEMBER 31, 2015

PMA No., Docket No.	Applicant	Trade name	Approval date
P150010, FDA–2015–M–3256	Fidia Farmaceutici, S.p.A.	HYMOVIS®	8/28/2015
P100006, FDA–2015–M–3257	Biomimetic Therapeutics, LLC	Augment® Bone Graft	9/1/2015
P140005, FDA–2015–M–3258	OrthogenRx, Inc.	GenVisc 850®	9/2/2015
P140015, FDA–2015–M–3376	Tandem Diabetes Care, Inc.	t:slim G4 Insulin Pump With Dexcom G4 Platinum CGM.	9/8/2015
P140016, FDA–2015–M–3377	Cook Medical Inc.	Zenith Alpha Thoracic Endovascular Graft	9/15/2015
P070015/S128, FDA–2015–M–3516	Abbott Vascular	XIENCE V and XIENCE nano Everolimus Eluting Coronary Stent System.	9/23/2015
P110019/S075, FDA–2015–M–3516	Abbott Vascular	XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Coronary Stent System, XIENCE Xpedition, XIENCE Xpedition SV and XIENCE Xpedition LL Everolimus Eluting Coronary Stent System, and XIENCE Alpine Everolimus Eluting Coronary Stent System.	9/23/2015
P050047/S044, FDA–2015–M–3519	Allergan	Juvéderm Ultra XC injectable gel	9/30/2015
P120010/S046, FDA–2015–M–4013	Medtronic, Inc.	MiniMed 530G System with Threshold Suspend featuring SmartGuard™ technology.	10/2/2015
P150003, FDA–2015–M–4014	Boston Scientific Corporation	SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System.	10/2/2015
P150013, FDA–2015–M–3520	Dako North America, Inc.	PD–L1 IHC 22C3 pharmDx	10/2/2015
P100034/S013, FDA–2015–M–4015	Novocure, Ltd.	Optune™ (Formerly the NovoTTF–100A System)	10/5/2015
P150025, FDA–2015–M–4016	Dako North America, Inc.	PD–L1 IHC 28–8 pharmDx	10/9/2015
P130009/S034, FDA–2015–M–4017	Edwards Lifesciences, LLC	Edwards SAPIEN XT™ Transcatheter Heart Valve, model 9300TFX, and Accessories.	10/9/2015
P150014, FDA–2015–M–4069	Roche Molecular Systems, Inc.	cobas® HBV	10/14/2015
P150015, FDA–2015–M–4018	Roche Molecular Systems, Inc.	cobas® HCV	10/14/2015
P140019, FDA–2015–M–4343	Cerapedics, Inc.	i-FACTOR™ Peptide Enhanced Bone Graft	11/3/2015
P120019/S007, FDA–2015–M–4344	Roche Molecular Systems, Inc.	cobas® EGFR Mutation Test v2	11/13/2015
P130028, FDA–2015–M–4434	Algostim, LLC	Algovita Spinal Cord Stimulation System	11/20/2015
P150019, FDA–2015–M–4728	Medtronic MiniMed	Paradigm Real-Time Revel System	12/7/2015
P010030/S056, FDA–2015–M–3521	ZOLL Manufacturing Corporation	LifeVest Wearable Cardioverter Defibrillator Models 3000, 3100, and 4000.	12/17/2015
P140030, FDA–2015–M–4947	Biotronik, Inc.	Astron Peripheral Self-Expanding Nitinol Stent System.	12/17/2015
P980044/S027, FDA–2015–M–4951	Seikagaku Corporation	VISCO–3™	12/21/2015

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: February 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02522 Filed 2–8–16; 8:45 am]

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