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 April 1, 2013, through June 30, 2013. 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, 2013, THROUGH JUNE 30, 2013

PMA No., Docket No.	Applicant	Trade name	Approval date
P120016, FDA–2013–M–0592	Cardiva Medical, Inc.	VASCADE Vascular Closure System (VCS)	January 31, 2013.
P070026/S004, FDA–2013–M–0462.	DePuy Orthopaedics, Inc.	DuPuy Ceramax Ceramic Total Hip System	April 2, 2013.
P960043/S080, FDA–2013–M–0464.	Abbott Vascular	PERCLOSE PROGLIDE Suture Mediated Closure System.	April 15, 2013.
P980040/S039, FDA–2013–M–0463.	Abbott Medical Optics, Inc.	TECNIS Toric 1-Piece Intraocular Lens (IOL) and the TECNIS Toric Calculator System.	April 15, 2013.
P080009, FDA–2013–M–0549	Ethicon Endo-Surgery, Inc.	SEDASYS Computer-Assisted Personalized Sedation System.	May 3, 2013.
P120019, FDA–2013–M–0594	Roche Molecular Systems, Inc.	COBAS EGFR Mutation Test	May 14, 2013.
P080003/S001, FDA–2013–M–0595.	Hologic, Inc.	Selenia Dimensions 3D System	May 16, 2013.
P030002/S027, FDA–2013–M–0724.	Bausch+Lomb, Inc.	TRULIGN Toric Posterior Chamber Intraocular Lens.	May 20, 2013.
P120014, FDA–2013–M–0709	bioMérieux, Inc.	THxID BRAF Kit for use on the ABI 7500 Fast DX Real-Time PCR Instrument.	May 29, 2013.
P060028, FDA–2013–M–0738	Mentor Worldwide LLC	MEMORYSHAPE Breast Implants	June 14, 2013.
P120012, FDA–2013–M–0758	Abbott Molecular, Inc.	Abbott RealTi*m*e HCV Genotype II, Abbott RealTi*m*e HCV Genotype II Control Kit, and Uracil-N-Glycosylase (UNG).	June 20, 2013.

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: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20085 Filed 8–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 October 16, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On October 16, 2013, the committee will discuss the supplemental new drug application 202057/S–005, VASCEPA (icosapent ethyl) capsules, submitted by Amarin Pharmaceuticals Ireland Ltd. VASCEPA is currently approved as monotherapy for the treatment of severe hypertriglyceridemia. This supplemental application proposes

concomitant use with an inhibitor of HMG-CoA reductase (statin) to reduce triglycerides, non-high density lipoprotein cholesterol, apolipoprotein B, low-density lipoprotein cholesterol, total cholesterol, and very low density lipoprotein cholesterol in adults with mixed dyslipidemia and coronary heart disease (CHD) or a CHD risk equivalent.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 30, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 20, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 23, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–20111 Filed 8–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Cooperative Research and Development Agreement Program: Invitation To Solicit Nonclinical and Clinical Research Proposals From NIH Intramural Research Program Scientists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Office of Technology Transfer (OTT), Office of the Director (OD), the National Institutes of Health (NIH), invites industry organizations (including corporations, partnerships, limited partnerships, and industrial development organizations); public and private foundations and nonprofit organizations to solicit research proposals from scientists across the NIH Intramural Research Program (IRP) for multiple focused research projects under a the NIH Cooperative Research And Development Agreement (CRADA) Program. This CRADA Program is an extension of collaboration opportunities solicited by NIH or developed on a one-on-one basis. As such, it is consistent with PHS Technology Transfer policy and the public health mission of the NIH. These collaboration opportunities are structured under the authority of 15 U.S.C. 3710a—Cooperative Research and Development Agreements. Note that the CRADA mechanism does not permit the transfer of funds from the NIH to a collaborator but does permit the collaborator to provide funding to the NIH researcher.

FOR FURTHER INFORMATION CONTACT: Ann Hammersla, J.D., Director, Division of Policy, Office of Technology Transfer, NIH, 6011 Executive Blvd., Suite 325, Rockville, MD 20852; Email: *hammerslaa@od.nih.gov*.

SUPPLEMENTARY INFORMATION: The NIH Wide CRADA Program is a means for a single collaborative research partner to coordinate a number of focused research projects across the IRP of the NIH Institutes and Centers (ICs). The CRADA Program will be driven by the collaborator's interest to solicit research proposals from NIH IRP scientists in multiple ICs for highly focused collaborative research in areas of mutual interest. NIH investigators' proposals responsive to a solicitation will be reviewed by their IC's Scientific Director to assure that: (1) The proposed project advances the mission of that IC, (2) the scientist has the resources to complete his or her part of the project, and (3) the IC supports the use of the investigator's time and resources. Once the research proposal is approved by the IC Scientific Director, the NIH IRP scientist(s) will submit to the soliciting organization the non-confidential, non-binding research proposal. NIH research proposals selected by the organization will be developed more fully and if appropriate under confidentiality agreements governing the confidentiality and use of such additional information. The collaboration will be governed by CRADA terms that address intellectual property rights, publications, and reporting obligations using the model CRADA as a basis for negotiation, see: *www.nih.gov/forms_model_agreements/forms_model agreements.aspx*.

For each collaboration, the CRADA will include a specific Research Plan, which delineates the scope of the NIH and collaborator's research to be conducted and establishes benchmarks to chronicle its progress. The CRADA will include a description of the resources to be contributed by the collaborator (e.g., scientific expertise, R&D support, proprietary materials, and funding), and the NIH IC (e.g., scientific expertise, R&D support, and proprietary materials). The CRADA statute does not permit the NIH to provide funding to a collaborator. The NIH is willing to work with each collaborator to establish a CRADA template agreement to be used by any IC interested in collaborating under this type of CRADA Program.

NIH Criteria for Submitting a Summary Research Proposal to a Collaborator's Solicitation

Alignment with NIH IC scientific mission and identified public health objectives;

Advancement of NIH IRP scientist's ongoing research or an extension of that research; and