electronic access to the guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria'' dated August 2013. The guidance document provides blood establishments that collect blood and blood components with recommendations for questioning and deferring donors of blood and blood components, and allowing their reentry, to reduce the risk of transfusion-transmitted malaria. This guidance document also provides recommendations for product management, including recommendations regarding product retrieval and quarantine, and notification of consignees of blood and blood components in the event that a blood establishment determines that blood or blood components have been collected from a donor who should have been deferred due to possible malaria risk. Finally, the guidance contains recommendations on the implementation of FDA's recommendations, including how licensed blood establishments must report to FDA the changes made to their donor history questionnaires to reflect the new donor deferral recommendations.

In the **Federal Register** of July 6, 2012 (77 FR 40068), FDA announced the availability of the draft guidance of the same title dated June 2012. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Significant changes to the guidance include: revisions to the definition of malaria-endemic area, malaria-endemic country and other terms used to assess a donor's risk of malaria based on history of travel or residence; and revisions to the recommendations regarding consignee notification and reporting of biological product deviations for acellular blood components collected from a donor at risk for malaria. Based on the revised definition of malaria-endemic area and current epidemiological data, donors who travel to the Mexican States of Quintana Roo or Jalisco would be eligible for donation without any deferral, provided the donors meet all other eligibility criteria. However, if malaria transmission in these States changes over time, the donor deferral recommendations would encompass donors who travel to these areas. The guidance announced in this notice finalizes the draft guidance dated June 2012, and supersedes the FDA memorandum to all registered blood establishments entitled ''Recommendations for Deferral of Donors for Malaria Risk,'' dated July 26, 1994.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 640 and 21 CFR 630.6 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19962 Filed 8–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–M–0462, FDA–2013–M–0463, FDA–2013–M–0464, FDA–2013–M–0549, FDA–2013–M–0592, FDA–2013–M–0594, FDA–2013–M–0595, FDA–2013–M–0709, FDA–2013–M–0724, FDA–2013–M–0738, and FDA–2013–M–0758]

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. 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]

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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