malaria based on history of travel or
terms used to assess a donor’s risk of
definition of malaria-endemic area,
guidance include: revisions to the
finalized. Significant changes to the
received several comments on the draft
same title dated June 2012. FDA
recommendations.
the new donor deferral
report to FDA the changes made to their
establishments must
recommendations, including how
been deferred due to possible malaria
transmitted malaria. This guidance
cOMPONENTS, and allowing their reentry,
product management, including
recommendations regarding product
notification and reporting of biological
report on the
deferral, provided the donors meet all
or Jerlisco would be
eligibility criteria. However, if
malaria transmission in these States
covers 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finalizes the draft guidance dated June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
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
commments 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/
GuidanceComplianceRegulatory
Information/Guidances/default.htm or


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[DOcket Nos. FDA–2013–M–0462, FDA–

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:
Nicolle 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>
<thead>
<tr>
<th>PMA No., Docket No.</th>
<th>Applicant</th>
<th>Trade name</th>
<th>Approval date</th>
</tr>
</thead>
</table>

II. Electronic Access

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


Leslie Kux, Assistant Commissioner for Policy.

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

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. 1501), 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. Bogansky, 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...