Total Annual Hours: 365.136. (For policy questions regarding this collection contact William Lehman at 410–786–1037. For all other issues call 410–786–1326.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Site Investigation for Durable Medical Equipment (DME) Suppliers; Use: CMS is mandated to identify and implement measures to prevent fraud and abuse in the Medicare program. To meet this challenge, CMS has moved forward to improve the quality of the process for enrolling suppliers into the Medicare program by establishing a uniform application for enumerating suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Implementation of enhanced procedures for verifying the enrollment information has also improved the enrollment process. As part of this process, verification of compliance with supplier standards is necessary. The site investigation form has been used in the past to aid the Medicare contractor (the National Supplier Clearinghouse and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services.

This site investigation form collects the same information as its predecessor, with the exception of one new yes/no question under the “Records and Telephone” section (question 11(a)) used to verify if the DMEPOS supplier maintains physician ordering/referring records for the supplies and/or services it renders to Medicare beneficiaries (if applicable). This information is required by section 1833(q) of the Social Security Act (the Act) which states that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) of the Act, be uniquely identified for all claims for services that are ordered or referred. Other information collected on this site investigation remains unchanged, but has been reformatted for greater functionality. Form Number: CMS–R–263 (OCN: 0938–0749); Frequency: Once; Affected Public: Private Sector—Business or other for-profits and not-for-profit institutions; Number of Respondents: 30,000; Total Annual Responses: 30,000; Total Annual Hours: 15,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Registration Application; Use: The CMS 855O allows a physician to receive a Medicare identification number (without being approved for billing privileges) for the sole purpose of ordering and referring Medicare beneficiaries to Medicare approved providers and suppliers. This new Medicare registration application form allows physicians who do not provide services to Medicare beneficiaries to be given a Medicare identification number without having to supply all the data required for the submission of Medicare claims. It also allows the Medicare program to identify ordering and referring physicians without having to validate the amount of data necessary to determine claims payment eligibility (such as banking information), while continuing to identify the physician’s credentials as valid for ordering and referring purposes. Since the physicians and non-physician practitioners submitting this application are not enrolling in Medicare to submit claims but are only registering with Medicare as eligible to order and refer, CMS believes changing the title from Medicare Enrollment Application to Medicare Registration Application better captures the actual purpose of this form.

Where appropriate, CMS has changed all references to enrollment or enrolling to registration and registering and Medicare billing number to National Provider Identifier. CMS also added a check box to allow physicians and non-physician practitioners to withdraw from the ordering and referring registry. A section to collect information on professional certifications was added for those practitioners who are not professionally licensed. Editorial and formatting corrections were made in response to prior comments received during the approval of the current version of this application. Other minor editorial and formatting corrections were made to better clarify the purpose of this application. Form Number: CMS–855O (OCN: 0938–1135); Frequency: Occasionally; Affected Public: Individuals; Number of Respondents: 48,500; Total Annual Responses: 48,500; Total Annual Hours: 24,125. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on May 29, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: OIRA_submission@omb.eop.gov.

Dated: April 24, 2012.

Martique Jones,
Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–10225 Filed 4–26–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Circulatory System 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: Circulatory System 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 June 13, 2012, from 8 a.m. to 6 p.m.


Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or FDA Advisory Committee Information Line, 1–800–747–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product.
area. Please call the Information Line for up-
to-date information on this meeting. 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 adequate notice. Therefore, you
should always check the Agency’s Web site
and call the appropriate advisory committee
hot line/phone line to learn about possible
modifications before coming to the meeting.

Agenda: On June 13, 2012, the committee
will do the following: (1) Review and vote on
information related to the premarket
approval application for the Edwards
SAPIEN Transcatheter Heart Valve sponsored
by Edwards Lifesciences. The Edwards
SAPIEN Transcatheter Heart Valve is
indicated for use in patients with
symptomatic severe aortic stenosis who have
high operative risk.

The Edwards SAPIEN Transcatheter Heart
Valve, model 9000TFX, sizes 23mm and
26mm and accessories implant system
consists of the following:

- A heterologous (bovine) pericardium
leafflet valve sutured within a stainless steel
mesh frame, with a polyester skirt. It is
offered in sizes 23 mm and 26 mm.

- The RetroFlex 3 Delivery System is used
to advance the bioprosthesis through the
RetroFlex sheath over a guidewire and to
track the bioprosthesis over the aortic arch
and for crossing and positioning in the native
valve. The delivery system also comes with
a sheath, introducer, loader, dilator, balloon
(pre-dilate the native annulus) and a crimmer.

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 June
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 May
29, 2012. 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
can 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 June 1, 2012.

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 James
Clark, Conference Management Staff, at
James.Clark@fda.hhs.gov or 301–796–5293 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).


Jill Hartzler Warner,
Acting Associate Commissioner for Special
Medications.

[FR Doc. 2012–10156 Filed 4–26–12; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic 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: Oncologic Drugs
Advisory Committee.

General Function of the Committee: To
provide advice and recommendations to the
Agency on FDA’s regular health
operations.

Date and Time: The meeting will be held
on June 20, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus,
Building 31, the Great Room, White Oak
Conference Center, (Rm. 1503), 10803 New
Hampshire Avenue, Silver Spring, MD
20903–0002. 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 Meeting
Information and Procedures” and then the
FDA White Oak Campus.” Please note that
visitors to the White Oak Campus must enter
through Building 1.

Contact Person: Caleb Briggs, Pharm.D.,
Center for Drug Evaluation and Research,
Food and Drug Administration, 10803 New
Hampshire Ave., WO31–2417, Silver Spring,
MD 20903–0002, (301) 796–9001, Fax: (301)
847–8533, email: ODAC@fda.hhs.gov, or FDA
Advisory Committee Information Line, 1–
800–741–8138 (301–443–0572 in the
Washington, DC area), to find out further
information regarding FDA advisory
committee information. Please review 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
and call the advisory committee information
line or visit our Web site at http://
www.fda.gov/AdvisoryCommittees/
default.htm to learn about possible
modifications before coming to the meeting.

Agenda: On June 20, 2012, during the
morning session, the committee will discuss
new drug application (NDA) 203213, with
the established name selumeparin sodium
injection, application submitted by sanofi-
aventis U.S. LLC. The proposed indication
(use) for this product is for the prophylaxis
of venous thromboembolism (VTE) in
patients receiving chemotherapy for locally
advanced or metastatic pancreatic or lung
cancer or for locally advanced or metastatic
solid tumors with a VTE risk score 23.

During the afternoon session, the
committee will discuss NDA 202714, with
the proposed trade name Kyprolis (carfilzomib)
for injection, application submitted by Onyx
Pharmaceuticals, Inc. The proposed indication
(use) for this product is for the treatment of patients with relapsed and
refractory (recursing and/or not
responsive to other treatments) multiple
myeloma who have received at least 2 prior
times of therapy that included a proteasome
inhibitor and an immunomodulatory agent.

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 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 June
6, 2012. Oral presentations from the public will be scheduled between
approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 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 May
29, 2012. 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