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 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 17, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–15570 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0443]

Scientific Evaluation of Modified Risk Tobacco Product Applications; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products is announcing a public workshop to obtain input on specific issues associated with the scientific evaluation of modified risk tobacco product (MRTP) applications. The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) establishes a requirement for persons to obtain an order from FDA before they can introduce or deliver for introduction into interstate commerce MRTPs and outlines the requirements that must be met before FDA will issue such an order. The Tobacco Control Act also directs FDA to get input from appropriate scientific and medical experts on the design and conduct of studies and surveillance required for assessment and ongoing review of MRTP applications. The purpose of the public workshop is to create a forum for appropriate scientific and medical experts and other interested stakeholders to provide input on these topics. FDA will take the information it obtains from the public workshop into account as it determines how best to implement the MRTPs provisions of the Tobacco Control Act. FDA is also opening a public docket to receive comments on these topics.

DATES: *Dates and Times:* The public workshop will be held on August 25, 2011, from 8:30 a.m. to 5:30 p.m., and on August 26, 2011, from 8:30 a.m. to 4 p.m. Individuals who wish to make a presentation at the public workshop must register by close of business on August 3, 2011. Submit either electronic or written comments to the docket by September 23, 2011.

Location: The public workshop will be held at the 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/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: *Contact Person:* Anuja Patel, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 4), FAX: 240–276–3761, e-mail: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop and Requests for Oral Presentation: If you wish to attend the workshop or make an oral presentation at the workshop, please e-mail your registration to *workshop.CTPOS@fda.hhs.gov* by close of business on August 3, 2011. Those without e-mail access may register by contacting Anuja Patel (*see Contact Person*). Please provide contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at *http://www.fda.gov/TobaccoProducts/default.htm.*

An open comment session will be held during the public workshop on August 25, 2011, from 11 a.m. to 12:30 p.m., during which comments from the public will be accepted. If you would like to make an oral presentation during the open comment session, you must indicate this at the time of registration. FDA has included questions for comment in section II of this document. You should identify the question number(s) you will address in your presentation and the approximate time requested for your presentation.

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation must check in at the registration table by 10 a.m. on August 25, 2011. In addition, we strongly encourage submitting comments to the docket (*see Comments*).

If you need special accommodations because of a disability, please contact Anuja Patel (see *Contact Person*) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit comments on any questions for comment in section II of this document by September 23, 2011. Submit electronic comments 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. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, President Obama signed into law the Tobacco Control Act, providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 911 (21 U.S.C. 387k), which prohibits the introduction or delivery for introduction of an MRTP into interstate commerce without an order from FDA.

MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. According to section 911(b)(1) of the FD&C Act, a tobacco product is considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease if its label, labeling, or advertising represents, either explicitly or implicitly, that:

- The product is less harmful or presents a lower risk of tobacco-related disease than one or more commercially marketed tobacco products; or
- The product or its smoke contains a reduced level of, presents a reduced exposure to, or is free of a substance.

A tobacco product is also considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease if the product's:

- Label, labeling, or advertising uses the words ''light,'' ''mild,'' or ''low,'' or similar descriptors; or
- Manufacturer has taken any action after June 22, 2009, directed to consumers through the media or otherwise (other than through the product's label, labeling, or advertising) that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a reduced risk of harm, tobacco-related disease, or exposure to a substance than one or more commercially marketed tobacco products.

Section 911(b)(2) of the FD&C Act

Before an MRTP can be introduced or delivered for introduction into interstate commerce, an application for the product must be filed with FDA, and the Agency must review the application and determine whether it is appropriate to issue an order under section 911(g). (*See* section 911(a), (d), and (g) of the FD&C Act.) Section 911(d) of the FD&C Act describes the required contents of an MRTP application, while section 911(g) of the FD&C Act describes the requirements for obtaining an order.

Section 911(g) of the FD&C Act sets forth two bases for obtaining an order from FDA for an MRTP application. Under section 911(g)(1), FDA shall issue an order only if FDA determines that an applicant has demonstrated that the product, as it is actually used by consumers, will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users, and
- Benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

Under section 911(g)(2), FDA may issue an order for MRTPs that may not satisfy the requirements under section 911(g)(1) (described previously) if FDA determines that an applicant has demonstrated that:

- Such an order would be appropriate to promote the public health;
- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for an order set forth in section 911(g)(1) of the FD&C Act; and
- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

Furthermore, for FDA to issue an order under section 911(g)(2), FDA must find that the applicant has demonstrated that:

- The magnitude of overall reductions in exposure to the substance or substances that are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to similar types of tobacco products then on the market unless such increases are minimal, and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- Issuance of an order is expected to benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

In making determinations regarding the benefit to the health of individuals and the population as a whole under section 911(g)(1) or (g)(2), FDA will take into account:

- The relative health risks the MRTP presents to individuals;
- The increased or decreased likelihood that existing tobacco product users who would otherwise stop using such products will switch to using the MRTP;
- The increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP;
- The risks and benefits to persons from the use of the MRTP as compared to the use of smoking cessation drug or device products approved by FDA to treat nicotine dependence; and
- Comments, data, and information submitted to FDA by interested persons.

Section 911(g)(4) of the FD&C Act

Each applicant receiving an order from FDA under section 911(g)(1) or (g)(2) will conduct postmarket surveillance and studies, either as a condition of receiving an order under section 911(g)(2), or as required by FDA for products receiving an order under section 911(g)(1). (*See* section 911(g)(2)(C)(ii) and 911(i)(1) of the FD&C Act.)

Section 911(h) of the FD&C Act describes additional conditions for marketing MRTPs. For example, under section 911(h)(1) of the FD&C Act, the advertising and labeling of an MRTP must enable the public to comprehend the information concerning modified risk and understand the relative significance of such information in the context of total health and in relation to all the diseases and health-related conditions associated with the use of tobacco products. Under section 911(h)(2) of the FD&C Act, FDA may require that a claim comparing an MRTP

to one or more commercially marketed tobacco products compare the MRTP to a commercially marketed tobacco product that is representative of that type of tobacco product on the market. Under that section, FDA may also require that the identity of the reference tobacco product and the percentage change and a quantitative comparison of the amount of the substance claimed to be reduced be stated in immediate proximity to the most prominent claim. Under section 911(h)(3) of the FD&C Act, FDA may require that an MRTP's label disclose other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or increase the risk of other diseases or health-related conditions associated with the use of tobacco products. Under that section, FDA may also require an applicant to label the product with conditions of use if the conditions of use may affect the risk of the product to human health. Section 911(h)(4) of the FD&C Act requires than an order issued under section 911(g)(1) of the FD&C Act be effective for a specified period of time. Furthermore, under section 911(h)(5) of the FD&C Act, FDA may require that MRTPs that are granted an order under section 911(g)(1) of the FD&C Act comply with requirements relating to advertising and promotion of the product.

Section 911(l) of the FD&C Act requires FDA to issue regulations or guidance (or any combination thereof) regarding the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Among other things, the regulations or guidance must:

- To the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under section 911(g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs (under 911(g)(1)) or is reasonably likely (under 911(g)(2));
- Include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;
- Establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate; and
- Establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception.

Section 911(l) of the FD&C Act

Section 911(l)(2) of the FD&C Act directs FDA to get input from appropriate scientific and medical experts on the design and conduct of studies and surveillance required for assessment and ongoing review of modified risk tobacco products.

II. Workshop Objectives and Issues for Discussion

The purpose of this public workshop is to obtain information and comments from appropriate medical and scientific experts, which may include academia, public health groups, regulators, manufacturers of tobacco products, health care professionals, interested industry, and professional associations, and the public about the scientific issues associated with assessment and ongoing review of MRTPs. The input from the public workshop is expected to provide valuable information to assist the Agency in developing guidance or regulations.

At the public workshop, FDA will provide relevant background information, including a brief summary of section 911 of the FD&C Act, as added by the Tobacco Control Act. The meeting will include scientific and medical expert speakers who will present on scientific and technical factors related to the evaluation of MRTPs. FDA anticipates that the key questions that will be considered at the public workshop are those listed in the paragraphs that follow. FDA is interested in receiving substantive scientific input on these questions at the meeting and in the docket. FDA will post the agenda and additional workshop background material 5 days before the workshop at: *http://www.fda.gov/TobaccoProducts/default.htm.*

A. Benefit to Individual Tobacco Users

Modified risk tobacco products have the potential to benefit individual tobacco users by reducing harm and the risk of tobacco-related disease compared to conventional tobacco products. FDA seeks comments and information on the following issues:

1. What scientific evidence would inform a determination that an MRTP, as actually used, will significantly reduce harm and the risk of tobacco-related disease to users? What types (if any) of scientific studies other than long-term epidemiological studies could show a significant reduction in harm and the risk of tobacco-related disease to users?

2. What scientific evidence would inform a determination that an MRTP, as actually used, presents a reasonable likelihood of a measurable and substantial reduction in tobacco-related morbidity or mortality among individual tobacco users?

B. Impact on the Health of the Population as a Whole

MRTPs may offer the potential for benefitting individual tobacco users by reducing the risk of tobacco-related morbidity or mortality associated with conventional tobacco products. However, these products could harm the health of the population as a whole if they lead to continued use of tobacco products in individuals who would otherwise have quit, resumption of tobacco use in individuals who previously quit (i.e., relapse), dual use among current tobacco users, or initiation of tobacco use among individuals who otherwise would not have used tobacco products. FDA seeks comments and information on the following issues related to the impact of an MRTP on the health of the population as a whole:

1. What scientific evidence would inform a determination of how an MRTP will actually be used by consumers once it is commercially marketed, and what are the strengths and limitations of different methods of studying actual consumer use?

2. What scientific evidence, including consumer perception data, would inform a determination of the effect an MRTP as it is proposed to be labeled and marketed will have on increasing initiation of tobacco use among non-users, decreasing or delaying cessation due to switching to the MRTP among current tobacco users, encouraging use of multiple tobacco products instead of complete switching among current tobacco users, and increasing relapse among previous tobacco users who have quit?

3. What scientific evidence would inform the measurement of potential benefits relative to potential harms to the general population to achieve an overall public health benefit?

C. Comparisons of MRTPs to Other Products

In making determinations regarding the benefit to the health of individuals and the population as a whole under either section 911(g)(1) or (g)(2), FDA will take into account, among other things, the relative health risks to individuals of the MRTP and the risks and benefits to users of the MRTP as compared to the use of smoking cessation drugs or devices approved to

treat nicotine dependence. (*See* section 911(g)(4) of the FD&C Act.) FDA seeks comments and information on the following issues:

1. What comparisons should be used in scientific studies intended to inform a determination of the effects of an MRTP on reducing the risk of tobacco-related disease to individual users relative to one or more commercially marketed tobacco products?

2. What comparisons should be used in scientific studies intended to inform a determination of the effects of an MRTP on reducing exposure to a harmful substance or substances?

3. What comparisons should be used in scientific studies intended to inform a determination of whether an MRTP will benefit or is likely to benefit the health of the population as a whole?

4. What scientific evidence would inform the evaluation of the risks and benefits of the use of an MRTP as compared to use of drug or device products approved to treat nicotine dependence?

D. Reduced Substance Exposure

Tobacco products are considered MRTPs if their label, labeling, or advertising represents, either explicitly or implicitly, that the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance, or that the product or its smoke does not contain or is free of a substance. (*See* section 911(b)(2)(A)(i) of the FD&C Act.) For FDA to issue an order regarding an MRTP application under section 911(g)(2), FDA must determine that the applicant has demonstrated that, among other things, the magnitude of the overall reductions in exposure to the substance or substances that are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances. Moreover, FDA must determine that the applicant has demonstrated that the MRTP, as actually used by consumers, will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless the increases are minimal and the reasonably likely overall impact of the use of the MRTP remains a substantial and measurable reduction in overall morbidity and mortality. FDA seeks comments and information on the following issues:

1. What scientific evidence would inform a determination that an MRTP (or its smoke) does not contain or contains a reduced level of a substance?

2. What scientific evidence would inform a determination that the reduction in exposure to a substance presented by an MRTP is substantial?

3. What scientific evidence would inform a determination that an MRTP as it is actually used by consumers will expose consumers to the specified reduced level of a substance?

4. What scientific evidence would inform a determination that an MRTP does not increase exposure to other harmful substances? If an MRTP does increase exposure to another harmful substance, what scientific evidence would inform a determination that any increase is minimal and, overall, there is still a likelihood of a measurable and substantial reduction in morbidity and mortality among individual tobacco users?

E. Consumer Perception of MRTPs

To issue an order under section 911(g)(2), FDA must find that the applicant has demonstrated that testing of actual consumer perceptions of the tobacco product, as it is proposed to be labeled and marketed, shows that consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or that it presents or has been demonstrated to present less risk of disease than one or more commercially marketed tobacco products. (*See* section 911(g)(2)(B)(iii) of the FD&C Act.) Furthermore, section 911(h)(1) requires FDA to ensure that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products. (*See* section 911(h)(1) of the FD&C Act.) FDA seeks comments and information on the following issues related to consumer perception:

1. What scientific evidence would inform a determination that consumers will not be misled by a representation that an MRTP or its smoke does not contain or contains a reduced level of a substance into believing that the product is or has been demonstrated to be less harmful, or presents, or has been demonstrated to present, less risk of disease than one or more other commercially marketed tobacco products?

2. What scientific evidence would inform a determination that consumers will comprehend the information concerning modified risk in an MRTP's advertising and labeling and understand the relative significance of such information in the context of total health and in relation to all the diseases and health-related conditions associated with the use of tobacco products?

F. Postmarket Surveillance and Studies of Commercially Marketed MRTPs

Each applicant receiving an order from FDA under section 911(g)(1) or (g)(2) will conduct postmarket surveillance and studies, either as a condition of receiving an order under section 911(g)(2), or as required for products receiving an order under section 911(g)(1). (See section 911(g)(2)(C)(ii) and 911(i)(1) of the FD&C Act.) Such surveillance and studies are designed to, among other things, determine the impact of an FDA order on consumer perception, behavior, and health, and enable FDA to review the accuracy of the determinations upon which the Agency based its order. (*See* section 911(g)(2)(C)(ii) and (i)(1) of the FD&C Act.) FDA seeks comments and information on the following issues related to postmarket surveillance and studies:

1. What types of postmarket studies could provide regular and long-term assessments of patterns of product use (*e.g.,* dual use, product switching) and the impact of the MRTP on quitting behavior, relapse, and initiation of tobacco use?

2. What types of postmarket studies could provide regular and long-term assessments of exposure levels to harmful substances?

3. What types of postmarket studies could provide regular and long-term assessments of applicable validated biomarkers and intermediate clinical endpoints?

4. What types of postmarket studies could provide regular and long-term assessments of health outcomes and mortality?

5. What types of postmarket studies could provide regular and long-term assessments of consumer perception of the MRTP and other tobacco products?

6. What types of postmarket surveillance (other than postmarket studies) could be used to ensure appropriate collection of data regarding the use, consumer perception, and health risks of an MRTP?

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (*see Comments*). A transcript will also be available in either hard copy or on CD–ROM, after submission of a

Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–15601 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

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 July 20 and 21, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1609, Silver Spring, MD 20993–0002, 301–796–6313, or FDA Advisory Committee Information Line, 1–800–741–8138 (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 timely 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 July 20, 2011, the committee will discuss, make recommendations, 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, model 9000TFX, sizes 23 millimeters (mm) and 26 mm and accessories implant system consists of the following:

- The Edwards SAPIEN Transcatheter Heart Valve consists of a heterologous (bovine) pericardium leaflet valve sutured within a stainless steel mesh frame, with a polyester skirt. It is offered in 2 sizes, a 23 mm and a 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 (used to pre-dilate the native annulus) and a crimper.

On July 21, 2011, the committee will discuss, make recommendations, and vote on information related to the humanitarian device exemption for the Berlin Heart EXCOR Pediatric Ventricular Assist Device (VAD) sponsored by Berlin Heart, Inc. The Berlin Heart EXCOR Pediatric VAD device is a pneumatically-driven extracorporeal ventricular assist device. It is designed to provide bridge-to-transplant mechanical support to the heart. The system consists of one or two extracorporeal blood pumps (univentricular or biventricular support), cannulae for the connection of the blood pumps to the atria and great arteries, and the IKUS Stationary Driving Unit (electro-pneumatic driving system).

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 July 14, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. 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 July 6, 2011. 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 July 8, 2011.

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 AnnMarie Williams, Conference Management Staff, at 301–796–5966, 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: *June 15, 2011.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–15539 Filed 6–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0104 (Formerly Docket No. 2007E–0001)]

Determination of Regulatory Review Period for Purposes of Patent Extension; METVIXIA

AGENCY: Food and Drug Administration, HHS.