gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or *http://www.regulations.gov.*

Dated: May 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11053 Filed 5–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1107]

Oxiplex®/SP Gel; FzioMed, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; 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 topic to be discussed is the Center for Device and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for Oxiplex®/SP Gel (OXIPLEX) submitted by FzioMed, Inc.—the sponsor for OXIPLEX. The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on scientific disputes between CDRH and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on June 10, 2014, from 8 a.m. to 6 p.m.

Location: The meeting will be held at the Hilton Washington DC/North, salons A, B, C, and D of the Ballroom, 620 Perry Pkwy., Gaithersburg, MD. The hotel's telephone number is 1–301–977–8900.

Contact Person: Pamela D. Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3611, Silver Spring, MD 20993, 301–796–5433, FAX: 301–847–8510, email: *pamelad.scott@fda.hhs.gov,* 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 affect 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.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions from persons other than FzioMed and CDRH may be made to the docket on or before June 3, 2014. 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. Identify all written and electronic comments and submissions with the docket number found in brackets in the heading of this document. All written and electronic comments and submissions will be considered to be publicly disclosable.

Oral presentations from persons other than FzioMed and CDRH will be scheduled between approximately 12:45 and 1:15 p.m. on June 10, 2014. If you wish to make an oral presentation during the meeting, you should register on or before May 27, 2014. Send registration information (including name, title, firm name, address, telephone, email, and FAX number), and requests to make oral presentations to Pamela D. Scott (see *Contact Person*). You should provide the docket number appearing in the heading of this notice. You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. The amount of time to be allotted to each presenter may be limited to provide opportunities to as many persons wishing to present as possible. 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 that session. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Pamela D. Scott will notify interested persons regarding their request to speak by June 2, 2014. On the day of the meeting scheduled open public speakers should identify themselves at the registration desk.

After the scheduled speakers have spoken, the Chair of the advisory committee may ask them to remain if the advisory committee wishes to question them further. The Chair may recognize unscheduled speakers should time allow.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing that, in accordance with section 515(g)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(g)(2)), a public advisory committee will review CDRH's denial of a PMA for OXIPLEX submitted by FzioMed—the sponsor for OXIPLEX.

On August 21, 2007, FzioMed submitted a PMA (PMA P070023) for OXIPLEX. OXIPLEX is an absorbable, clear, viscoelastic gel designed to be applied in the lower back during lumbar spine surgery. The device's proposed indication is for use as a surgical adjuvant in adult patients with primary leg pain and severe baseline back pain undergoing first surgical intervention (i.e., open or endoscopic posterior lumbar laminectomy, laminotomy, or discectomy) for diagnosed unilateral herniation of lumbar intervertebral disc material associated with radiculopathy. The proposed intended use is for one-time use, up to 3 milliliters, after hemostasis during wound closure, as an adjunct to primary surgical intervention to improve patient outcomes by reducing leg pain, back pain and neurologic symptoms.

On October 9, 2012, CDRH issued a decision upholding a not approvable letter in response to the PMA P070023 for OXIPLEX. CDRH determined that PMA P070023 is not approvable based on its conclusion that the data and information offered in support of the PMA do not provide a reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2) of the FD&C Act.

On November 5, 2012, FzioMed requested administrative review of CDRH's decision to uphold its not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (see § 814.44 (21 CFR 814.44(f)(2))), FzioMed's petition for review (petition) stated that, in accordance with § 814.44(f), FzioMed

considered the decision to uphold the not approvable letter to be a denial of approval of PMA P070023 under § 814.45. Pursuant to section 515(d)(4) of the FD&C Act, FzioMed requested review of this denial under section 515(g)(2) of the FD&C Act (petition is available in Docket No. FDA–2012–P–1107).

Accordingly, as required by § 814.45(e)(3), CDRH issued an order denying approval of the PMA for OXIPLEX on October 21, 2013. Pursuant to section 515(g)(2) of the FD&C Act, on October 25, 2013, FDA granted FzioMed's petition for review of the order denying PMA P070023. In accordance with section 515(g)(2) of the FD&C Act, the Office of the Commissioner is referring PMA P070023 and the basis for the order denying its approval to the Medical Devices Dispute Resolution Panel (the panel), an advisory committee of experts established, in part, to receive referrals of petitions for advisory committee review under section 515(g)(2)(B) of the FD&C Act. The panel for this review will consist of nine persons, qualified by training and experience to evaluate the clinical and scientific basis of CDRH's order denying approval of the PMA. After independent study of the data and information furnished to it by the Office of the Commissioner, and other data and information before it, the panel will, during the meeting, discuss, evaluate, make recommendations, and vote on the issues in dispute based on the statement of issues described below. A transcript of the meeting will serve as a report and recommendation with respect to CDRH's order denying approval. (See section 515(g)(2)(A) of the FD&C Act.) Together with the underlying data and information before the panel, the transcript of the meeting will be submitted to FDA's Chief Scientist, who is an official authorized to perform all delegable functions of the Commissioner and is the Commissioner's designee for this matter.

The Office of the Commissioner will make the transcript of the meeting public in accordance with section 515(g)(2)(C) of the FD&C Act. The Office of the Commissioner will also provide a copy of the transcript to FzioMed and CDRH and will offer FzioMed and CDRH the opportunity to submit comments on the panel's recommendations before a final order is rendered. In accordance with section 515(g)(2)(C) of the FD&C Act, the Chief Scientist will issue an order either affirming or reversing the order denying PMA P070023 and, if appropriate, approving or denying approval of the PMA.

II. Meeting Issues and Process

A. Issues

The scientific questions for the panel relate to whether the information provided by FzioMed is sufficient to provide a reasonable assurance of safety and effectiveness for OXIPLEX's proposed indications. Key to a determination regarding effectiveness is whether the product will provide clinically significant results to a significant portion of the target population. (See 21 CFR 860.7(e).)

Over the course of CDRH's review of OXIPLEX, FzioMed submitted data from four peer-reviewed, published clinical studies in an effort to demonstrate safety and effectiveness. The clinical studies included a pilot study and a pivotal study, both of which were conducted in the United States, and two studies conducted outside of the United States in China and Italy (the OUS studies). The pivotal study was a randomized, controlled, double-blinded multicenter study designed to evaluate the efficacy of OXIPLEX in the reduction of postoperative pain and symptoms and to evaluate the safety of applying OXIPLEX during lumbar disc surgery by comparing a group of patients undergoing lumbar surgery alone and a group undergoing the same surgery with the use of OXIPLEX. FzioMed maintains that, although the pivotal study did not show a statistically significant reduction in leg pain for OXIPLEX in the study patient population as a whole, the study did demonstrate OXIPLEX to be effective for the subgroup of patients with leg pain and severe baseline back pain (SBBP):

> For those subjects with both leg pain and severe baseline back pain, which comprised 55% of the total study population, . . . improvement in leg pain from baseline to the 6-month visit was statistically significantly greater for Oxiplex subjects compared to control subjects (P=0.0123), with an 18% greater improvement in leg pain in the Oxiplex group compared to controls. (Petition at 7–8.)

In addition, FzioMed submitted data from the two OUS studies that, according to FzioMed, provide confirmatory evidence of the safety and efficacy of OXIPLEX in the severe back pain subgroup.

In denying PMA P070023, CDRH concluded that the effect observed in the SBBP subgroup in the pivotal study was not adequate to support approval because it stemmed from what CDRH characterized as FzioMed's ''exploratory subgroup analysis.'' CDRH further determined that the OUS studies do not confirm the results of improvement shown in postoperative leg pain in the SBBP subgroup from the pivotal study because: (1) Differences in subject population and study endpoints among the three studies preclude pooling the data; (2) the Chinese clinical study was not initially designed to assess the treatment effect in the SBBP subgroup, and review of the quartile of patients with the most severe baseline back pain in the study did not demonstrate a treatment effect for OXIPLEX at either the 30- or 60-day endpoint; and (3) the Italian clinical study was not truly randomized, resulting in important baseline differences between the control and treatment groups that preclude meaningful comparison between the two groups, and few study subjects had baseline back pain of the severity considered in the SBBP subgroup of the pivotal study.

FzioMed contests the scientific bases for CDRH's determination that the evidence from the pivotal study and the two OUS studies does not provide a reasonable assurance of the device's safety and effectiveness for the device's proposed indications. First, FzioMed contends that the agency should place greater weight on the treatment results for the SBBP subgroup in the pivotal study. While acknowledging that ''severe'' was not prospectively defined in identifying the SBBP subgroup, the company notes that the statistical analysis plan did prospectively identify baseline back pain as a covariate for analysis. FzioMed maintains that analysis of this subgroup was justified and executed in a manner consistent with the approved statistical analysis plan. Second, FzioMed maintains that differences in study population among the clinical studies submitted to FDA actually strengthen support for the effectiveness of OXIPLEX:

> The fact that consistent results were observed using the LSOQ [Lumbar Spine Outcomes Questionnaire] and the Visual Analogue Scale (VAS), and that these results were demonstrated at short (60 days), intermediate (6 months) and long-term (3 years) follow-up intervals supports the robustness of the data and confirms that the results observed in the U.S. pivotal study did not occur by chance. (Petition at 13.)

Third, FzioMed argues that CDRH improperly rejected the submitted OUS studies as confirmatory evidence of safety and effectiveness, based on, among other things, inappropriate subgroup analyses and improper restrictions on study design.

CDRH and FzioMed have agreed that, in order to demonstrate clinically significant results for a significant portion of the target population from the adjunctive use of OXIPLEX for the proposed SBBP indications, the

submitted information must demonstrate, based on patients' self-assessment under validated pain scales, at least a 10 percent difference in the mean leg pain reduction from baseline pain to 6-month postoperative residual pain in favor of Oxiplex, when the mean difference between the treatment and control groups is divided by the mean reduction in leg pain in the control group. This assumes at least a 50 percent reduction in baseline to 6-month residual pain in the control group.

Questions for the panel to consider relative to safety and effectiveness are:

1. With respect to the pivotal study:

a. Is it scientifically and statistically valid to rely on analysis of the SBBP subgroup of the pivotal study to support, in part, a determination of reasonable assurance of effectiveness for the proposed SBBP indications?

b. Did CDRH give the effect observed in the SBBP subgroup of the pivotal study sufficient weight in evaluating OXIPLEX's effectiveness for the proposed SBBP indications?

2. With respect to the Chinese clinical study (Confirmatory Study #1):

a. Is it scientifically and statistically valid to rely on analysis of the SBBP subgroup as confirmatory evidence of effectiveness for the proposed SBBP indications?

b. In evaluating whether OXIPLEX provides clinically significant results for the proposed SBBP indications, is it scientifically and statistically valid to look at the treatment effect for OXIPLEX observed for the quartile of patients (N=17) with the most severe baseline back pain (VAS score ≥6.2) at the 30- and 60-day endpoints?

3. With respect to the Italian case series (Confirmatory Study #2): Does the study design enable a scientifically and statistically valid comparison between the treatment and control groups for the proposed SBBP indications?

4. Do the differences in study design for the pivotal study and the OUS studies prevent considering all three studies in the aggregate to evaluate whether OXIPLEX provides statistically and clinically significant results for the proposed SBBP indications?

5. When reviewed in total, do the data and other information submitted for OXIPLEX provide a reasonable assurance of effectiveness for the proposed SBBP indications (i.e., do the data and information demonstrate, based on patients' self-assessment under validated pain scales, at least a 10 percent difference in the mean leg pain reduction from baseline pain to 6-month post-operative residual leg pain in favor of OXIPLEX, when the mean difference between the treatment and control groups is divided by the mean reduction in pain in the control group, assuming at least a 50 percent reduction in baseline to 6-month residual pain in the control group)?

6. When reviewed in total, do the data and other information submitted for OXIPLEX provide a reasonable assurance of safety for the proposed SBBP indications? For there to be ''reasonable assurance of safety,'' valid scientific evidence must enable a determination that the probable benefits to health from use of OXIPLEX for the proposed SBBP indications outweigh any probable risks.

B. Process

Although no statute or regulation requires that separation of functions be applied to this review proceeding under section 515(g)(2) of the FD&C Act, FDA is adopting the following measures to ensure impartiality and promote efficiency. First, the Office of the Commissioner has formed two teams. The first, the Substantive Team, handles all decisions on any issues or matters that either relate directly to the merits of the review proceeding or are the subject of a dispute between CDRH and FzioMed, which are both parties to this proceeding. The second team, the Administrative Team, handles all undisputed procedural matters related to the administration of the panel meeting. The Administrative Team ensures that it keeps the parties apprised of all significant procedural decisions. Moreover, the Administrative Team refers the parties to the Substantive Team if either or both of the parties have concerns about the manner in which the Administrative Team has resolved a procedural issue.

To promote efficiency and facilitate the flow of information between the Office of the Commissioner and the parties, the agency is not requiring that all communications between the parties and the Office of the Commissioner be made part of the public record. However, until the Office of the Commissioner issues an order either affirming or reversing the order denying approval of PMA P070023, the Office of the Commissioner will not engage, and has not engaged, in any communication concerning the merits of the review proceeding with anyone participating as a party to the hearing or any person outside the agency unless the communication is made part of the public record. Communications between the parties and the Administrative Team that are not part of the public record will be limited to discussion of procedural issues and questions.

For the purposes of this proceeding, members of CDRH are considered to represent CDRH unless specifically designated to advise the Office of the Commissioner as a member of the Substantive Team or Administrative Team. All other members of FDA are available to advise and participate with the Office of the Commissioner on matters related to this proceeding.

At the meeting, each party will be provided 1 hour and 45 minutes during the first portion of the meeting to present relevant information or views orally. The parties may use the allotted time as desired, consistent with an orderly meeting, and may be accompanied by additional persons, who may present relevant information or views. The parties will subsequently be allowed 15 minutes for rebuttal. During the panel's open discussion, the panel members may pose questions to, or seek requests for clarification from, FzioMed and/or CDRH. Thereafter, each party will be allocated 15 minutes for summation, after which panel deliberation and voting will occur.

FDA welcomes the public's attendance at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you need special accommodations due to a disability, please contact AnnMarie Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3611, Silver Spring, MD 20993, 301–796–5966, FAX: 301–847–8505, email: *Annmarie.Williams@fda.hhs.gov* 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.

Because this is a public meeting before an advisory committee, it is subject to our regulations concerning the policy and procedures for electronic media coverage of public agency administrative proceedings (21 CFR 10.200 through 10.206). These procedures are primarily intended to expedite media access to our public proceedings. Representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record our public administrative proceedings, including the testimony of witnesses in the proceedings. Accordingly, the parties and nonparty participants, and all other interested persons, are directed to § 10.200 through 10.206, for a more

complete explanation of those regulations' effect on this meeting.

Documents filed in this matter are available for public review under Docket No. FDA–2012–P–1107 in the Division of Dockets Management (see *Procedure*) between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents at *http://www.regulations.gov.* FDA intends to make background material, including briefing materials for the panel provided by CDRH and FzioMed, available to the public no later than 2 business days before the meeting. If FDA is unable to provide the background material 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 available in the Division of Dockets Management (see *Procedure*) and at *http://www.regulations.gov* after the meeting.

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

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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11048 Filed 5–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Studies of Fumonisin Exposures.

Date: June 5, 2014.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, Room 3076, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Scientific Review Officer, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS).

Dated: May 8, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–10993 Filed 5–13–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Microfluidic Assay Platforms.

Date: June 10, 2014.

Time: 7:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Michael P Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–496–9659, *reillymp@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Short-Term Training to Promote Diversity in Health Research.

Date: June 10, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Stephanie L Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301–443–8784, *constantsl@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Microfluidic Blood Assays.

Date: June 10, 2014.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Michael P Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–496–9659, *reillymp@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Blood and Vascular Systems Response to Sepsis (R01).

Date: June 11–12, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7198, Bethesda, MD 20892, 301–435–0293, *goltrykl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Mentored Transition to Independence.

Date: June 12–13, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0285, *Pintuccig@nhlbi.nih.gov.*