II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Blumberg, S.J., and J.V. Luke, ''Wireless Substitution: Early Release of Estimates From the National Health Interview Survey, July-December 2010,'' *(http://www.cdc.gov/nchs/nhis.htm),* National Center for Health Statistics, June 2011.
2. Lee, S., J.M. Brick, E.R. Brown, et al., ''Growing Cell-Phone Population and Noncoverage Bias in Traditional Random Digit Dialing Telephone Health Surveys,'' *Health Services Research,* 45: 1121–1139, 2010.
3. Voigt, L.F., S.M. Schwartz, D.R. Doody, et al., ''Feasibility of Including Cellular Telephone Numbers in Random Digit Dialing for Epidemiologic Case-Control Studies,'' *American Journal of Epidemiology,* 173: 118–126, 2011.
4. Yen, S.T., K.L. Jensen, and C.-T.J. Lin, ''Awareness and Perceived Risk of Pesticide and Antibiotic Residues in Food: Socioeconomic Variations Among U.S. Consumers,'' *Food Protection Trends,* 26: 654–661, 2006.
5. Lin, C.-T.J. and S.T. Yen, ''Knowledge of Dietary Facts Among U.S. Consumers,'' *Journal of the American Dietetic Association,* 110: 613–618, 2010.
6. American Association for Public Opinion Research (AAPOR), ''New Considerations for Survey Researchers When Planning and Conducting RDD Telephone Surveys in the United States With Respondents Reached via Cell Phone Numbers,'' *(http://www.aapor.org/Cell_Phone_Task_Force_Report.htm),* 2010.
7. Keeter, S., ''The Impact of Cellular Phone Noncoverage Bias on Polling in the 2004 Presidential Election,'' *Public Opinion Quarterly,* 70: 88–98, 2006.
8. Blumberg, S.J. and J.V. Luke, ''Reevaluating the Need for Concern Regarding Noncoverage Bias in Landline Surveys,'' *American Journal of Public Health,* 99: 1806–1810, 2009.
9. Keeter, S., C. Kennedy, A. Clark, et al., ''What's Missing From National Landline RDD Surveys? The Impact of the Growing Cell-Only Population,'' *Public Opinion Quarterly,* 71: 772–792, 2007.

Dated: December 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31389 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0326]

Biologics Price Competition and Innovation Act of 2009; Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the proposed recommendations for a user fee program for biosimilar biological products for fiscal years (FYs) 2013 through 2017.

DATES: The public meeting will be held on Friday, December 16, 2011, from 9 a.m. to 1 p.m. Registration to attend the meeting must be received by December 14, 2011. See section III.B of this document for information on how to register for the meeting. Submit either electronic or written comments by January 6, 2012.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993–0002. Please note that visitors to the White Oak Campus must enter through Building 1.

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. All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the public meeting (see section III.C of this document).

FOR FURTHER INFORMATION CONTACT: Rokhsana Safaai-Jazi, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1164, Silver Spring, MD 20993–0002, (301) 796–4463, *Fax:* (301) 847–8443, Email: *BiosimilarsUserFeeProgram@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations for a user fee program for biosimilar biological products (biosimilars user fee program) for FYs 2013 through 2017. On March 23, 2010, President Obama signed into law the Affordable Care Act (Pub. L. 111–148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. (See sections 7001 through 7003 of the Affordable Care Act.) Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. (See section 7002(f)(3)(A) of the Affordable Care Act.) Accordingly, under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), the fee for a biologics license application (BLA) is currently the same regardless of whether the application is submitted under the new 351(k) approval pathway or the preexisting 351(a) approval pathway.

The authority conferred by the Federal Food, Drug, and Cosmetic Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a biosimilars user fee program for FYs 2013 through 2017. (See section 7002(f)(1) of the Affordable Care Act.) The BPCI Act provides that FDA must consult with a range of groups, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups (public stakeholders), and regulated industry (industry stakeholders), in developing the recommendations. As described in section II of this document, FDA consulted with public and industry stakeholders from June 2011 through September 2011.

The BPCI Act requires that FDA must publish the recommendations for a biosimilars user fee program in the **Federal Register** and provide a period of 30 days for the public to provide written comments on the recommendations.

FDA is also required to hold a meeting at which the public may present its views on such recommendations. After consideration of such public views and comments, FDA is to revise the recommendations as necessary and transmit them to Congress by January 15, 2012.

This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, FDA will revise the recommendations as necessary and present them to Congress. (See section 7002(f)(1) of the Affordable Care Act.) Additional information is provided in this document to help potential meeting participants better understand the proposed recommendations.

II. Proposed Biosimilars User Fee Program Recommendations

In developing proposed recommendations for a biosimilars user fee program, FDA has conducted discussions with regulated industry and consulted with public stakeholders, as required by the law. FDA initiated the public consultation process on November 2 and 3, 2010, by holding a public hearing at which stakeholders and other members of the public were given an opportunity to present their views on issues associated with the implementation of the BPCI Act. (See 75 FR 61497, October 5, 2010.)[1] Among other issues relating to the implementation of the BPCI Act, FDA solicited public comment on the following questions related to a biosimilars user fee program:

- If the existing fee structure under the Prescription Drug User Fee Act (PDUFA) were to be considered as a model in establishing a user fee structure for applications and supplements for proposed biosimilar and interchangeable biological products, what factors and changes should FDA take into consideration, and why?
- What factors should FDA take into account when considering whether to recommend that user fees for biosimilar and interchangeable biological products should also be used to monitor safety after approval?

In the **Federal Register** of May 10, 2011 (76 FR 27062),[2] FDA published a notice requesting public input on FDA's proposed principles for development of a biosimilars user fee program, FDA's proposed structure for a biosimilars user fee program that would adhere to these principles, and proposed performance goals for this program.

From June 2011 through September 2011, FDA conducted negotiations with regulated industry, and consultation meetings with public stakeholders, concerning development of recommendations for a biosimilars user fee program. FDA posted minutes of these meetings on its Web site at *http://www.fda.gov/ForIndustry/UserFees/ucm268124.htm.*

The proposed biosimilars user fee program for FYs 2013 through 2017 addresses many of the top priorities identified by public and industry stakeholders, and the most important challenges identified within FDA. The proposed biosimilars user fee program is similar to the PDUFA program in that it includes fees for marketing applications, manufacturing establishments, and products. However, there are some differences because of the nascent state of the biosimilars industry in the United States. For example, there are no currently marketed biosimilar biological products; accordingly, the recommended biosimilars user fee program includes fees for products in the development phase in order to generate fee revenue in the near-term and to enable sponsors to have meetings with FDA early in the development of biosimilar biological product candidates.

As in all of FDA's other medical product user fee programs, under the proposed biosimilars user fee program, user fee funding would supplement dedicated non-user fee funding to ensure sufficient resources for the Agency's biosimilars review program. In each fiscal year, in order to spend biosimilars user fees, FDA would be required to have available and allocate at least $20 million, adjusted for inflation, in non-user fee money for biosimilars review activities.

Under the proposed biosimilars user fee program, FDA would be authorized to spend biosimilars user fees on Agency activities related to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and investigational new drug applications (INDs). It would also include development of the scientific, regulatory, and policy infrastructure necessary for review of biosimilar biological product applications, such as regulation and policy development related to the review of biosimilar biological product applications, and development of standards for products subject to review and evaluation. It would cover FDA activities at the application stage, such as review of advertising and labeling prior to approval of a biosimilar biological product application or supplement; review of required postmarketing studies and postmarketing studies that have been agreed to by sponsors as a condition of approval; the issuance of action letters that communicate decisions on biosimilar biological product applications; and inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements (but not inspections unrelated to the review of biosimilar biological product applications and supplements). Finally, it would include some activities at the post-approval stage, such as postmarketing safety activities with respect to biologics approved under biosimilar biological product applications or supplements.

A. Proposed Fees

The four types of fees under the proposed biosimilars user fee program are summarized in this section II.A.

1. Biosimilar Product Development Fees

FDA's proposed biosimilars user fee program includes initial and annual biosimilar product development (BPD) fees for biosimilar biological products in development. The initial BPD fee would be due upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological application for a product, or within 5 days after FDA grants a request for a ''biosimilar biological product development meeting'' (BPD Meeting) for a product. (BPD Meetings are further described in section II.B.7 of this document.)

Additionally, under the proposed BPD program, if FDA determines that an IND is intended to support a biosimilar biological product application for a product, each person that has submitted an IND before the date of enactment of the legislation authorizing the biosimilars user fee program would also be subject to the initial BPD fee. A sponsor would be assessed only one initial BPD fee per product. Regardless of the number of proposed indications for the biosimilar biological product, the sponsor would pay one BPD fee per product. The initial BPD fee for each of the FYs 2013 through 2017 would be equal to 10 percent of the fee established for a human drug

[1] *http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf.*

[2] *http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf.*

application under PDUFA for that fiscal year.

Beginning in the next fiscal year after a sponsor has paid the initial BPD fee for a product, the sponsor would pay an annual BPD fee on or before October 1 of each year, until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in the BPD program for the product. A sponsor that has not submitted an IND for the product may discontinue participation in the BPD program by submitting a written declaration to FDA affirming that the sponsor has no present intention of further developing the product as a biosimilar biological product. A sponsor that has submitted an IND for the product would be able to effectuate the discontinuation only after withdrawing the IND as specified in 21 CFR part 312. A sponsor must discontinue participation in the BPD program by August 1 of the year of discontinuation to avoid incurring the fee that otherwise would be due on October 1. A sponsor that maintains an IND for the product after submitting a marketing application for the product that was accepted for filing would not pay the annual BPD fee for that product.

A sponsor that has discontinued participation in the BPD program for a product would be required to pay a reactivation fee in order to resume participation in the BPD program for that product. The reactivation fee would be equal to twice the initial BPD fee for that fiscal year. The reactivation fee would be due within 5 days after FDA grants a request for a BPD Meeting for the product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product, whichever is earlier. A sponsor that pays a reactivation fee for a product would be required to pay the annual BPD fee for the product beginning in the next fiscal year.

If a sponsor has failed to pay the initial BPD fee, annual BPD fee, or reactivation fee as required, FDA would not provide a BPD Meeting relating to the biosimilar biological product for which the fees are owed. Also, except in extraordinary circumstances, if a sponsor that owes BPD fees submits an IND that FDA determines is intended to support a biosimilar biological product application, FDA would not consider the sponsor's IND to have been received under section 505(i)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(2)). In addition, if a sponsor that owes BPD fees has an existing IND that FDA determines is intended to support a biosimilar biological product application, FDA would prohibit the sponsor from continuing the investigation (this action would be referred to as ''financial hold''). Finally, if a sponsor has failed to pay BPD fees as required, then any biosimilar biological product application or supplement submitted by that sponsor would be considered incomplete and would not be accepted for filing until all fees owed by the sponsor have been paid.

2. Marketing Application Fee

FDA estimates that the cost of reviewing an application for licensure of a biosimilar biological product will be comparable to the cost of reviewing an application for licensure of a biological product under section 351(a) of the PHS Act. FDA therefore proposes to set the marketing application fee for a biosimilar biological product equal to the fee established for a human drug application under PDUFA, minus the cumulative amount of any BPD fees (including any reactivation fees) paid for the product that is the subject of the application. The feedback and consultation that FDA expects to provide to sponsors during the biosimilar biological product development phase is expected to improve the efficiency of the biosimilar biological product development process and the quality of submitted marketing applications. Therefore, FDA considers the BPD phase fees, and the deduction of paid BPD fees from the associated marketing application fee payment, to be a reasonable approach to shift resources forward to the point in development where FDA review is currently being sought by sponsors.

3. Establishment Fees and Product Fees

Because the complexity and level of effort required for FDA oversight of manufacturing and postmarketing safety issues for products licensed under section 351(k) of the PHS Act is expected to be comparable to that required for products licensed under section 351(a), FDA proposes setting biosimilar biological product establishment and product fees equal to the establishment and product fees under PDUFA for any fiscal year. FDA anticipates a modest level of funding from these sources initially because only biosimilar biological products that are approved for marketing would be subject to these fees.

B. Proposed Performance Goals and Procedures

The full description of the proposed performance goals and procedures for the biosimilars user fee program can be found in the draft biosimilars user fee commitment letter (draft commitment letter) posted on FDA's Web site at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf.* The proposed performance goals and procedures are described in this section II.B with reference to the section of the draft commitment letter where more detailed information can be found.

1. Review Performance Goals

The proposed biosimilars review program would include review performance goals for biosimilar biological product application submissions and resubmissions, supplements with clinical data, and original manufacturing supplements. Further information concerning these review performance goals can be found in section I of the draft commitment letter. The review performance goals are summarized in tables 1 and 2 of this document.:

TABLE 1—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS

Submission cohort	Performance goal				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Within 10 Months of the Receipt Date					
Original Biosimilar Biological Product Application Submissions	70%	70%	80%	85%	90%

TABLE 1—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS—Continued

Submission cohort	Performance goal				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Within 6 Months of the Receipt Date					
Resubmitted Original Biosimilar Biological Product Applications	70%	70%	80%	85%	90%

TABLE 2—PERFORMANCE GOALS FOR ORIGINAL AND RESUBMITTED SUPPLEMENTS

Submission	Performance goal
Original Supplements with Clinical Data	90% Within 10 Months of the Receipt Date.
Resubmitted Supplements with Clinical Data	90% Within 6 Months of the Receipt Date.
Manufacturing Supplements	90% Within 6 Months of the Receipt Date.

2. First Cycle Performance Goals

The proposed biosimilars review program includes first cycle review performance goals for original biosimilar biological product applications and supplements with clinical data. For 90 percent of applications and supplements with clinical data, FDA's goal would be to inform the applicant of any substantive review issues identified during the initial filing review within 74 calendar days of the receipt date. In addition, for 90 percent of applications and supplements with clinical data, FDA's goal would be to inform the applicant of the planned review timeline for the application within 74 calendar days of the receipt date. Section II of the draft commitment letter contains further information concerning these performance goals.

3. Review of Proprietary Names To Reduce Medication Errors

The proposed biosimilars review program includes proprietary name review performance goals. For proprietary names submitted during the biosimilar biological product development phase, FDA's goal would be to review 90 percent within 180 days of receipt. For proprietary names submitted with the biosimilar biological product application, FDA's goal would be to review 90 percent within 90 days of receipt. Section III of the draft commitment letter contains further information concerning these performance goals.

4. Major Dispute Resolution

The proposed biosimilars review program includes a major dispute resolution performance goal. For procedural or scientific matters involving the review of biosimilar biological product applications and supplements that cannot be resolved at the signatory authority level, FDA's goal would be to respond to 90 percent of decision appeals within 30 calendar days of FDA's receipt of the written appeal, provided that certain conditions are met. Section IV of the draft commitment letter contains further information concerning this performance goal.

5. Clinical Holds

The proposed biosimilars review program includes a clinical hold performance goal. FDA's goal would be to respond to 90 percent of sponsors' complete responses to a clinical hold within 30 days of FDA's receipt of the complete response submission. Section V of the draft commitment letter contains further information concerning this performance goal.

6. Special Protocol Assessment

The proposed biosimilars review program includes procedures and performance goals for special protocol assessments. Under the proposed program, provided that certain conditions are met, upon specific request by a sponsor, the Agency would evaluate certain protocols and related issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor. FDA's goal would be to provide a written response to the sponsor that includes a succinct assessment of the protocol and answers to the questions posed by the sponsor. For FYs 2013 and 2014, FDA's goal would be to respond to 70 percent of the requests within 45 days of FDA's receipt of the protocol and specific questions. For FY 2015, FDA's goal would be to respond to 80 percent of the requests within the 45-day time frame; for FY 2016, 85 percent, and for FY 2017, 90 percent. Section VI of the draft commitment letter contains further information concerning this performance goal.

7. Meeting Management Goals

FDA proposes performance goals and procedures regarding meetings related to sponsors' biosimilar biological product development programs. Further information concerning these goals can be found in section VII of the draft commitment letter. These goals and procedures would apply to Biosimilar Initial Advisory Meetings and BPD Meetings. Under the proposed program, a Biosimilar Initial Advisory Meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the PHS Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. It does not include any meeting that involves substantive review of summary data or full study reports. A BPD Meeting is any meeting, other than a Biosimilar Initial Advisory Meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application. The four types of BPD Meetings are as follows:

- A BPD Type 1 Meeting is a meeting that is necessary for an otherwise stalled drug development program to proceed (*e.g.,* meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

- A BPD Type 2 Meeting is a meeting to discuss a specific issue (*e.g.,* proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. BPD Type 2 Meetings include substantive review of

summary data, but does not include review of full study reports.

• A BPD Type 3 Meeting is an in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. This type of meeting includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

• A BPD Type 4 Meeting is a meeting to discuss the format and content of a biosimilar biological product application or supplement submitted under section 351(k) of the PHS Act.

The proposed review program includes performance goals for responses to meeting requests. Specifically, for 90 percent of BPD Type 1 Meeting requests, FDA's goal would be to notify the requester in writing of the date, time, place, and format for the meeting, as well as expected Center participants, within 14 calendar days of FDA's receipt of the request and meeting package. For 90 percent of BPD Type 2, 3, and 4 Meeting requests and Biosimilar Initial Advisory Meeting requests, FDA's goal would be to notify the requester in writing of the date, time, place, and format for the meeting, as well as expected Center participants, within 21 calendar days of FDA's receipt of the request and meeting package.

The proposed review program also includes performance goals for scheduling meetings within target time frames. The target time frames for each of the five meeting types are as follows:

TABLE 3—TARGET TIME FRAMES FOR MEETING TYPES

Meeting type	Timeframe after receipt of meeting request and meeting package
Biosimilar Initial Advisory Meeting	Meeting should occur within 90 calendar days of FDA receipt.
BPD Type 1 Meeting	Meeting should occur within 30 calendar days of FDA receipt.
BPD Type 2 Meeting	Meeting should occur within 75 calendar days of FDA receipt.
BPD Type 3 Meeting	Meeting should occur within 120 calendar days of FDA receipt.
BPD Type 4 Meeting	Meeting should occur within 60 calendar days of FDA receipt.

The performance goals for each meeting type are as follows:

• For FY 2013, 70 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2014, 70 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2015, 80 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2016, 85 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

• For FY 2017, 90 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings are held within the target time frame.

Under the proposed program, in order for a meeting to qualify for these performance goals, certain conditions would need to be met. First, the meeting request and meeting package must include the information outlined in the draft commitment letter. Second, FDA must concur that the meeting will serve a useful purpose (*i.e.,* it is not premature or clearly unnecessary). If FDA determines that a different type of meeting is more appropriate, it may grant a meeting of a different type than requested, which may require the payment of a BPD fee before the meeting will be provided. If a BPD fee is required and the sponsor does not pay the fee within the required time frame, the meeting will be cancelled. If the sponsor pays the BPD fee after the meeting has been cancelled because of non-payment, the target time frame for the meeting will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.

FDA's goal would be to provide meeting minutes within 30 days of the date of the meeting for 90 percent of Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings. Finally, FDA's goal would be to develop and publish for comment draft guidance on Biosimilar Initial Advisory Meetings and BPD Type 1, 2, 3, and 4 Meetings by the end of the second quarter of FY 2014.

III. What information should you know about the public meeting?

A. When and where will the public meeting occur? What format will FDA use?

We will convene a public meeting to hear the public's views on the proposed recommendations for a biosimilars user fee program. We will conduct the meeting on December 16, 2011, at FDA's White Oak Campus (see **ADDRESSES**). The meeting will include a presentation by FDA and a series of panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry) to provide input on the proposed recommendations. We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

B. How do you register for the public meeting or submit comments?

If you wish to attend this meeting, please register by email at: *BiosimilarsUserFeeProgram@fda.hhs.gov* by December 14, 2011. Your email should contain complete contact information for each attendee, including: Name title, affiliation, address, email, address, and phone 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 based on space limitations. Registrants will receive confirmation once they have been accepted. On-site registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. If you need special accommodations because of disability, please notify FDA by email to *BiosimilarsUserFeeProgram@fda.hhs.gov* or Rokhsana Safaai-Jazi (see **FOR FURTHER INFORMATION CONTACT**) at least 4 days before the meeting.

In addition, 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. To ensure consideration, all comments must be received by January 6, 2012.

C. Will meeting transcripts be available?

As soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov.* It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be made 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 (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

IV. Additional Information on the BPCI Act

The following sources of information on FDA's Web site may serve as useful information:

- The **Federal Register** document that announced the November 2010 public hearing and requested public comments is available at *http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)
- Comments submitted in response to the November 2010 public hearing document can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0477.
- The **Federal Register** notice document that requested notification of stakeholder intention to participate in consultation meetings in December 2010 is available at *http://edocket.access.gpo.gov/2010/pdf/2010-30713.pdf.*
- The **Federal Register** notice that requested input on the comments relating to the development of a user fee program for biosimilar and interchangeable biological product applications in May 2010 is available at *http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf.* Additional information regarding implementation of the BPCI Act is available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031.*

Dated: December 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31499 Filed 12–5–11; 4:15 p.m.]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neurodegeneration, Signaling and Plasticity.

Date: December 13–15, 2011.

Time: 12:15 p.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joanne T Fujii, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 30, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31391 Filed 12–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–1103]

Merchant Marine Personnel Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Merchant Marine Personnel Advisory Committee (MERPAC). This Committee advises the Secretary of the Department of Homeland Security on matters related to personnel in the U.S. merchant marine, including but not limited to training, qualifications, certification, documentation, and fitness standards.

DATES: Applicants should submit a cover letter and resume in time to reach the Alternate Designated Federal Officer (ADFO) on or before February 6, 2012.

ADDRESSES: Applicants should send their cover letter and resume to the following *address:* Commandant (CG–5221), Attn MERPAC, U.S. Coast Guard, 2100 2nd St. SW., Stop 7126, Washington DC 20593–7126; or by calling (202) 372–1408; or by faxing (202) 372–1926; or by emailing to *rogers.w.henderson@uscg.mil.* This notice is available in our online docket, USCG–2011–1103, at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rogers W. Henderson, ADFO of MERPAC; telephone (202) 372–1408 or email at *rogers.w.henderson@uscg.mil.*

SUPPLEMENTARY INFORMATION: MERPAC is a Federal advisory committee established under the authority of section 871 of *The Homeland Security Act of 2002,* Title 6, United States Code, section 451. This committee is established in accordance with and operates under the provisions of the *Federal Advisory Committee Act* (FACA) (Title 5, United States Code, Appendix). MERPAC advises the Secretary of the Department of Homeland Security on matters relating to personnel in the U.S. merchant marine, including but not limited to training, qualifications, certification, documentation, and fitness standards. The Committee will advise, consult with, and make recommendations reflecting its independent judgment to the Secretary.

MERPAC is expected to meet approximately twice a year as called for by its charter, once at or near Coast Guard Headquarters, Washington, DC, and once elsewhere in the country. It may also meet for extraordinary purposes. Its subcommittees and working groups may also meet to consider specific tasks as required.

We will consider applications for six positions that expire or become vacant on June 1, 2012. To be eligible, you should have experience in the following areas of expertise: One member for marine educators representing the viewpoint of State Maritime Academies; one member for marine educators