DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Initial Review Group; Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: October 29, 2009.

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

Agenda: To review and evaluate grant applications.

Place: The Legacy, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Anne Krey, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892. 301–435–6908. *ak41o@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 25, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23723 Filed 9–30–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Child Health and Human Development Initial Review Group; Reproduction, Andrology, and Gynecology Subcommittee.

Date: October 30, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Dennis Leszczynski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute, of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–2717, *leszczyd@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 25, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23720 Filed 9–30–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 12, 2009, 8 a.m. to October 13, 2009, 12 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 22, 2009, 74 FR 48269–48273.

The meeting will be held October 13, 2009 to October 14, 2009. The meeting time and location remain the same.

The meeting is closed to the public.

Dated: September 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–23597 Filed 9–30–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program To Evaluate Proposed Proprietary Name Submissions; Procedures To Register for Participation and Submit Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opportunity for pharmaceutical firms (applicants) to participate in a voluntary 2-year pilot program for the evaluation of proposed proprietary names to be conducted by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). The pilot program will enable participating pharmaceutical firms to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review, as outlined in the FDA concept paper entitled ''PDUFA Pilot Project Proprietary Name Review.'' This document describes procedures to register and submit data for applicants who wish to have their proposed proprietary names evaluated under the pilot program.

DATES: FDA will begin accepting requests to register for the voluntary pilot program on October 1, 2009.

ADDRESSES: Submit written requests for single copies of the concept paper to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The concept paper may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the concept paper.

FOR FURTHER INFORMATION CONTACT:

Carol Holquist, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993–0002, e-mail: *proprietarynamereview@fda.hhs.gov* with the subject line identified as ''PNR Pilot Program for CDER/DMEPA;'' or

Ele Ibarra-Pratt, Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch (HFM–602), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, e-mail: *CBERAPLB@fda.hhs.gov* with the subject line identified as ''PNR Pilot Program for CBER/APLB.''

SUPPLEMENTARY INFORMATION:

I. Background

In title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), Congress reauthorized and expanded the Prescription Drug User Fee program for fiscal years 2008 to 2012 (PDUFA IV). In performance goals agreed to in conjunction with the reauthorization of PDUFA IV, FDA agreed to publish a concept paper on and implement a pilot program to enable pharmaceutical firms participating in the pilot program to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. (See section IX.B at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*.) This process is consistent with other areas of drug review in which FDA evaluates data generated by firms rather than producing such data independently. FDA agreed to conduct a public meeting to discuss the content of the concept paper, which describes the following: (1) The logistics of the pilot program, (2) proposed recommendations for carrying out a proprietary name review, and (3) the way FDA intends to review submissions made under the pilot program. In keeping with the performance goals:

- On June 5 and 6, 2008, FDA held a public technical meeting (see meeting notice at 73 FR 27001, May 12, 2008), to discuss a draft concept paper describing the pilot program and FDA's thinking about how pharmaceutical firms could participate in the pilot program to evaluate proposed proprietary names and submit the data generated to FDA for review. FDA considered comments received at the meeting and submitted to the public docket.
- In the **Federal Register** of October 7, 2008 (73 FR 58604), FDA announced the availability of the concept paper entitled ''PDUFA Pilot Project Proprietary Name Review.'' The concept paper provides information to pharmaceutical firms about how to evaluate proposed proprietary names at the new drug application (NDA) or biologics license application (BLA) phase or investigational new drug application (IND) phase (before NDA or BLA submission) or when an abbreviated new drug application (ANDA) is submitted, and to submit the data generated from those evaluations to FDA for review.

In addition to developing the concept paper for the pilot program, FDA announced the availability of a draft guidance for industry entitled ''Contents of a Complete Submission for the Evaluation of Proprietary Names'' (draft proprietary names submission guidance) (73 FR 71009, November 24, 2008).[1] FDA also announced the availability of the source code and supporting technical documentation for the Phonetic Orthographic Computer Analysis (POCA) software program, an analytic tool designed to help identify drug and biologic names and medical terminology that are phonetically and orthographically similar to one another (74 FR 7450, February 17, 2009). POCA is one analytic tool that FDA uses to review proposed proprietary drug and biologic names.

II. PDUFA Pilot Program Proprietary Name Review Logistics

A. Overview

As discussed in the concept paper (section III of PDUFA Pilot Program—Logistics), applicants should contact the appropriate FDA center to register to participate in the pilot program before making their proprietary name submissions (see **FOR FURTHER INFORMATION CONTACT** and **DATES**). This document describes the following procedures for implementing the pilot program:

- Who the FDA points-of-contact are to register for participation,
- How to register by e-mail and what information to provide,
- When and where to send proposed proprietary name submissions, and
- What type of information to include in a complete submission to support parallel reviews of a proposed proprietary name.

B. Registration Is Required To Participate in the Pilot Program

As discussed in the concept paper, FDA will strive to include a cross-section of applicants that represent large, medium, and small companies during the 2-year program. FDA hopes that 25 to 50 proposed proprietary name submissions will be received and reviewed under the pilot program. To achieve this goal and to manage workload within the PDUFA IV timelines, FDA will only be able to accept an average of one to two submissions per month. Consequently, it will be necessary to register to participate before making a proposed proprietary name submission under the pilot program. To determine if space is available for an applicant to participate in the pilot program and agree on a date to make its planned submission, applicants should contact the designated point-of-contact for the appropriate center by e-mail as described in the following two sections of this document.

1. Registration for CDER Review

For proposed proprietary names that are being submitted as part of an IND, NDA, BLA, ANDA, or supplement reviewed by CDER, contact Carol Holquist by e-mail at *proprietaryname review@fda.hhs.gov*. Applicants should provide the following information in the e-mail for registration:

- E-mail subject heading: ''PNR Pilot Program for CDER/DMEPA,''
- First sentence in e-mail should indicate: ''Request for Registration in PNR Pilot Program,''
- Company name,
- Name of U.S. regulatory contact (include telephone number and e-mail address),
- Name of entity conducting proprietary name analysis (applicant company or third-party vendor),
- Application type (IND, NDA, BLA, ANDA, or supplement) and application number,

[1] The draft proprietary names submission guidance is not intended to address the PDUFA IV performance goal of developing and implementing a pilot program for evaluating proposed proprietary names, or other PDUFA IV performance goals. Rather, the draft proprietary names submission guidance, when finalized, is intended to promote prevention of medication errors by assisting industry in the submission of complete product information that will help FDA to evaluate the safety of proposed proprietary drug and biological product names, taking into account other factors that, in association with the name, can contribute to medication errors. Persons with access to the Internet may obtain the draft proprietary names submission guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

• Proposed proprietary name (identify primary and alternate proprietary name, if any), and

• Approximate (requested) month for intended submission.

2. Registration for CBER Review

For biological drug products that are the subject of an IND, NDA, BLA, or supplement reviewed by CBER, contact Ele Ibarra-Pratt by e-mail at *CBERAPLB@fda.hhs.gov*. Applicants should provide the same information listed previously in section II.B.1 of this document, except that the e-mail subject heading should be: ''PNR Pilot Program for CBER/APLB.''

C. FDA Will Confirm Registration

FDA will respond to an applicant's e-mail request for registration to participate in the voluntary pilot program. The FDA point-of-contact will determine if the requested date of submission, by month, is available. If the requested date is available, FDA will e-mail the applicant confirming the applicant's registration in the pilot program.

If the applicant's requested date of submission, by month, is *not* available, FDA will propose an alternate date for the applicant to make the proprietary name submission under the pilot program. FDA will confirm the applicant's registration to participate once the applicant replies to FDA's e-mail acknowledging the acceptability of the alternate date.

If the alternate date is not acceptable to the applicant, the applicant should promptly notify FDA by e-mail. If an alternate date cannot be agreed upon and/or the applicant does not wish to participate in the pilot program, the applicant should so state in the e-mail response to FDA. An applicant that is not registered in the pilot program will submit its proposed name to the FDA for analysis and evaluation using FDA's traditional approach to the review of proposed proprietary names (see the draft proprietary names submission guidance).

D. Submissions Under the Pilot Program

1. When To Submit

Applicants registered in the pilot program should send their submissions to FDA for receipt within the first 2 business days of the agreed month. If the submission is not received on the first 2 business days of the agreed month, workload priorities may affect FDA's ability to review the proposed proprietary name as scheduled under the pilot program and FDA may convert the submission to a traditional review.

2. What to Submit—Content of Submission for Parallel Reviews

For all proprietary name submissions, the first page of the submission should include the statement ''REQUEST FOR PROPRIETARY NAME REVIEW'' in bold, capital letters. This statement should be immediately followed by the header ''PILOT PROGRAM'' in bold, capital letters.

Applicants should separate the data contained in the single submission into two separate sections to enable parallel reviews by FDA as follows:

• *Section I* should be labeled ''TRADITIONAL REVIEW'' and should contain the proposed proprietary name information that is submitted under FDA's traditional practice. For more information, see the draft proprietary names submission guidance and section III of Appendix B (Proposed Template for a Pilot Program Submission) of the concept paper. If this information is submitted as part of the pilot program, it is not necessary to submit it to the agency again.

• *Section II* should be labeled ''PILOT REVIEW'' and should contain the comprehensive evaluation of the proposed proprietary name, including the information and data listed in Appendix B of the concept paper. Only the data for the applicant's primary proposed proprietary name should be submitted. If the applicant has identified an alternate proprietary name, requests for the data regarding that name will be made only if FDA decides that the primary proposed proprietary name is not acceptable, after the decision is communicated to the applicant (see section II.E.1 of this document, Process to Request FDA Review of an Alternate Proposed Proprietary Name).

Although *Sections I* and *II* are contained in a single submission, the applicant should ensure that the data contained in each section can be reviewed independently. Data should not be cross-referenced; each section should encompass all of the data elements required for a complete submission. The prominent identification of the two sections of proposed proprietary name information will maintain the validity of the independent parallel reviews.

All proprietary name submissions under the pilot program will be screened for completeness (i.e., submission of information needed to evaluate the proprietary name). Applicants will be notified in writing if the submission does not contain all of the information needed to conduct the parallel reviews. Once the proposed proprietary name submission is considered complete, the submission will be reviewed within the PDUFA IV review performance goal timeframes [2] (i.e., IND—180 days from receipt of complete submission; NDA or BLA—90 days from receipt of complete submission).

3. How To Submit—Paper or Electronic Form

Submissions may be in paper or electronic form. For paper submissions, applicants should submit three copies of the submission to the same address as the original product application with which the proposed proprietary name is associated. Submit packages for proposed proprietary names for drugs, including biologics, that are the subject of an IND, NDA, BLA, or supplement to be reviewed by CDER to:

Center for Drug Evaluation and Research,
Food and Drug Administration,
Documents and Records Section,
5901–B Ammendale Road,
Beltsville, MD 20705–1266.

Submit packages for proposed proprietary names for biological drug products that are the subject of an IND, NDA, BLA, or supplement to be reviewed by CBER to:

Center for Biologics Evaluation and Research,
Document Control Center (HFM–602),
1401 Rockville Pike, rm. 200N,
Rockville, MD 20852–1448.

For electronic submissions, applicants should refer to FDA's Web site ''Electronic Common Technical Document (eCTD)'' at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm* and at *http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm163685.htm*. Refer specifically to the following documents on the Web page:

• Guidance for industry on ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications,''

• eCTD Backbone File Specifications for Module 1, and

• FDA eCTD Table of Contents Headings and Hierarchy.

Applicants are encouraged to use the Electronic Submissions Gateway (ESG) to submit regulatory information. For information on the use of the ESG, refer

[2] For proposed proprietary names that are submitted in an ANDA, the PDUFA IV performance goal timeframes do not apply.

to *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*.

4. Communications Concerning the Planned Submission

Applicants participating in the pilot program should contact the appropriate center point-of-contact by e-mail (see **FOR FURTHER INFORMATION CONTACT**) 120 days prior to the intended date of the proposed proprietary name submission to discuss specific details of the planned submission. If applicants plan to use alternative or additional methods to evaluate the safety of their proposed proprietary name(s), they should inform the appropriate center 120 days prior to their planned submission date. FDA does not have the resources to review the proposed alternative methodologies with the intent of coming to agreement with an applicant on the appropriateness of these alternative methodologies prior to submission. In such cases, FDA will review the alternative methodologies during the review of the actual submission.

If applicants have questions concerning the planned submission under the pilot program, they should contact the appropriate center point-of-contact by e-mail (see **FOR FURTHER INFORMATION CONTACT**) to discuss their questions. If necessary, applicants will be asked to submit their questions in writing; in some cases, a teleconference or face-to-face meeting to discuss the planned submission may be appropriate.

E. Process To Request FDA Review of an Alternate Proposed Proprietary Name

If, after parallel reviews of the proprietary name submission, FDA informs the applicant that the primary proposed proprietary name is unacceptable, the applicant should confirm in writing that it would like its previously identified alternate proposed proprietary name to be reviewed or submit a different alternate proprietary name. At this time, the applicant can request to have the alternate proprietary name evaluated by FDA under the pilot program or by the traditional review method. If the request is to have the alternate proprietary name reviewed under the pilot program, the applicant should submit the comprehensive evaluation of the alternate proposed proprietary name, including the information and data described in section II.D.2 of this document. If the request is to have the alternate proprietary name evaluated by the traditional method, the applicant may reference the information previously submitted for parallel review of the proposed primary proprietary name (*Section I* of the pilot program submission labeled ''TRADITIONAL REVIEW'').

A new proprietary name review clock for an alternate proposed proprietary name will not start until:

(1) The applicant has confirmed to the appropriate center, in writing, that it would like its alternate proprietary name evaluated by traditional review method or

(2) FDA receives the applicant's submission of an alternate proposed proprietary name along with the comprehensive information for section II ''PILOT REVIEW'' described in section II.D.2 of this document.

For either review method requested (traditional or pilot), the same PDUFA IV review performance goal timeframes apply to the review of the submission of an alternate proposed proprietary name (i.e., IND—180 days from receipt of complete submission; NDA or BLA—90 days from receipt of complete submission).

If the applicant requests that its alternate proprietary name be evaluated under the pilot program, the agency will take into account the date of the alternate proprietary name submission as it relates to the PDUFA IV goal for the application. The responsible center will use discretion to determine whether the agency will conduct a parallel review of the applicant's analysis or only a proprietary name evaluation using FDA's traditional approach. Although FDA would ideally also review the applicant's completed proprietary name analysis for the alternate name under the pilot program, resources may not permit such a review. Factors such as staffing will be used in making this determination.

F. Duration and Evaluation of the Pilot Program

At the end of fiscal year 2011, or after accruing 2 years of experience with pilot program submissions, FDA intends to evaluate the pilot program to determine whether to have applicants perform their own proprietary name analysis and submit resulting data to FDA for review. The results of this pilot program and recommended additions and/or changes to methods based on the reported results will be discussed in a future public meeting. Following that meeting, FDA will publish a draft guidance describing the best test methods for proprietary name evaluation.

III. Paperwork Reduction Act of 1995

The information collection provisions of this pilot program, excluding the submission of information that is part of the agency's traditional review of proprietary names, have been submitted to the Office of Management and Budget (OMB) for review, as required by section 3507 of the Paperwork Reduction Act of 1995. The provisions were approved and assigned OMB control number 0910–0648. This approval expires September 30, 2012. The proprietary name information submitted as part of the traditional review of proprietary names is approved under OMB control numbers 0910–0001 and 0910–0338. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

Persons with access to the Internet may obtain the concept paper at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf*.

Dated: September 25, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–23620 Filed 9–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services, Program Expansion Supplement Grant Award

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice to award a Program Expansion Supplement Grant.

CFDA Number: 93.710.

Legislative Authority: The legislative authority is provided in the American Recovery and Reinvestment Act of 2009 (ARRA) [Pub. L. 111–5]. Additional legislative authority and requirements are provided in Section 674(b)(2)(B) of the Community Services Block Grant Act (CSBG), as amended, by the Community Opportunity Accountability, and Training and Educational Services (Coats Human Services Reauthorization Act of 1998) [Pub. L. 105–285].

Amount of Award: $500,000.

Project Period: July 1, 2009–June 30, 2010.

Summary: The Office of Community Services (OCS) announces the award of a $500,000 single source program