findings, and report the findings generically to all interested parties.

DATES: Letter of interest must be received within 90 calendar days of publication in the **Federal Register**.

ADDRESSES: Mining companies able to provide NIOSH with mine sites for this research should submit a letter of interest to the NIOSH Pittsburgh Research Laboratory (PRL) Director. The letter should provide the name of the mine and a brief description of the anticipated sealing plans. Any questions should be addressed by phone or e-mail. Please send letter of interest to: R. Güner Gürtunca, PhD, NIOSH Pittsburgh Research Laboratory (PRL), 626 Cochrans Mill Road, Post Office Box 18070, Pittsburgh, PA 15236, telephone (412) 386–6601, E-mail *GGurtunca@cdc.gov*.

Background: Recent research reports published by NIOSH and the U.S. Army Corps of Engineers describe the potential for explosive methane mixtures to develop within sealed areas of underground coal mines. The composition and behavior of the atmosphere within sealed areas are not scientifically well-understood. Areas of interest include the extent and nature of explosive mixtures of gases, how the composition of these mixtures change over time, whether methane layering exists, the homogeneity of the atmosphere, and how barometric pressure changes impact the atmosphere behind seals.

Description: To conduct these measurements, NIOSH will deploy a tube bundle system (TBS) at the mine site for a period of 2 to 5 months (usually not more than 3 months). A TBS is a mechanical system for collecting and analyzing atmospheric samples continuously from anywhere in a mine. The TBS that NIOSH plans to use is a system that is currently being successfully deployed in many Australian underground coal mines. NIOSH seeks three to four underground coal mines throughout the U.S. to cooperate in this study. Underground coal mines covering at least one square mile and producing a medium to high volume of methane are needed. Sampling will be conducted one mine at a time. Either longwall or room-and-pillar mines are acceptable. NIOSH wants to deploy the system in a variety of geological conditions. A soon-to-be-abandoned coal mine is another option for deployment of the TBS.

Prior to sealing, NIOSH will install plastic sample tubing throughout the mine and the future sealed area. This should require a few days to accomplish and will require minimal effort from the cooperating mine. NIOSH will need to be present during the sealing process to insure that the tubing is properly installed through the seals. After sealing, NIOSH will monitor the composition of the atmosphere throughout the sealed area during the initial methane-accumulation phase and for several months thereafter until stability of the sealed atmosphere develops. Collected data will not be analyzed on a real time basis other than to insure that the system is properly working.

NIOSH will require the following assistance from mining company personnel:

- Site-specific guidance concerning the area to be sealed and how to most efficiently run the sampling tube out of the mine to the sampling analysis location.
- Transportation to and from the sealed area during the installation phase of the TBS and to occasionally check the status of the TBS underground.
- A surface location to locate the sampling trailer.
- For a mine site to be acceptable to NIOSH for this testing, the cooperating mine must be installing 120 psi seals that meet the current design standard.
- After installation, NIOSH will require little assistance from mining company personnel until NIOSH is ready to remove the system from the mine when some transportation assistance will be needed.

After the data is analyzed, the cooperating mine will be provided the data pertaining to its mine. NIOSH will present and/or publish data in a manner that does not identify the cooperating mines. Cooperating mines will have the opportunity to review publications and presentations by NIOSH prior to their release. While NIOSH will not identify the mines in its publications, the identity of cooperating mines may be subject to release in response to a request for documents made under the Freedom of Information Act. This announcement does not obligate NIOSH to enter into an agreement with any respondent.

FOR FURTHER INFORMATION CONTACT: R. Güner Gürtunca, PhD, NIOSH Pittsburgh Research Laboratory (PRL), 626 Cochrans Mill Road, Post Office Box 18070, Pittsburgh PA, 15236, telephone (412) 386–6601, e-mail *GGurtunca@cdc.gov*.

Dated: April 6, 2009.

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. E9–8462 Filed 4–13–09; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

ACTION: Notice.

SUMMARY: For many decades, the pediatric medical community, the public health community, and government agencies have recognized a range of questions regarding the use of therapeutics in children, including the shortage of clinical studies of drugs in children resulting in inadequate labeling for pediatric use. The lack of appropriate labeling results in off-label use of prescription drugs in many children and for many conditions. Contributing factors to this frequent off-label use of drugs in pediatrics include the rarity of some conditions in children with limited patient availability, the ethical concerns regarding the conduct of clinical trials in children, the lack of accurate information about which drugs are used by children, and the lack of long-term data on the medications that are frequently used.

Several steps have been taken in response to the growing awareness of the knowledge gaps that exist in pediatric therapeutics. The BPCA was originally enacted in January 2002 and reauthorized in September 2007, with the overall purpose of improving the level of information about pharmaceuticals used to treat children (*http://www.fda.gov/opacom/laws/pharmkids/contents.html*). The BPCA outlines a number of goals, including the identification and prioritization of therapeutic needs in pediatrics, especially drugs, biologics, or indications that require study. The legislation also calls for the conduct of pediatric research to learn more about the efficacy and safety of drugs in children as well as the training of experts needed to address the knowledge gaps in pediatric pharmacology. To identify drugs in need of further study, the BPCA mandates that the National Institutes of Health (NIH), in consultation with the U.S. Food and Drug Administration (FDA) and experts in pediatrics, develop

a process for prioritizing needs in pediatric therapeutics and publish a priority list at least every 3 years, starting in September 2008. In this notice, we will summarize past efforts to prioritize off-patent drugs that need further study as mandated by the BPCA 2002 and describe the plans for identifying needs in pediatric therapeutics as authorized by the BPCA 2007.

DATES: The list is effective upon publication.

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), 6100 Executive Boulevard, Suite 4A–01, Bethesda, MD 20892–7510, e-mail *taylorpe@mail.nih.gov* or *BestPharmaceuticals@mail.nih.gov*, telephone 301–496–9584 (not a toll-free number).

SUPPLEMENTARY INFORMATION: In the **Federal Register** Notice of January 21, 2003 (Vol. 68, No. 13), the NICHD announced the first list of off-patent drugs to be considered for study and described the process used in developing this list. Prioritization of drugs on the list was based in general on three major factors: (1) Frequency of use in the pediatric population, (2) severity of the condition being treated, and (3) potential for providing a health benefit in the pediatric population. These factors follow from the original BPCA legislation, which required NIH to consider (among other criteria) for each drug ''*whether new pediatric studies concerning the drug may produce health benefits in the pediatric population.*''

During the initial years of the BPCA prioritization process (2003–2005), the NICHD identified many individual drugs and indications that required further dosing, efficacy, and safety information. In 2005, based on the input of pediatric experts, an alternative approach was proposed that included identifying and prioritizing pediatric conditions and therapeutic approaches for those conditions. This proposed condition-based approach would allow us to identify gaps in scientific knowledge, determine key research agendas in pediatric medicine, evaluate the treatments of these conditions, and compare the use of drugs within a therapeutic class (both on- and off-patent). This approach would also allow us to obtain focused expertise in specific therapeutic areas that would help elucidate the scientific gaps within the prioritized area.

Update on BPCA Conditions/ Therapeutic Areas

In 2006, the NICHD and the FDA, in collaboration with pediatric experts, considered an alternative approach for prioritization—from a drug/indication approach to a condition-based approach. Please refer to the **Federal Register** Notice of April 25, 2006 (Volume 71, No. 79), and the **Federal Register** Notice of March 28, 2007 (Volume 72, No. 59), for a complete review of the previous prioritization process and therapeutic categories considered under the 2002 BPCA legislation. In addition, an update on the status of all drugs previously listed under BPCA 2002 is provided at *http://bpca.nichd.nih.gov*. The following conditions have been listed to date, with brief updates on progress and/or current NICHD commitments.

- 2006

—*Oncology:* Four clinical trials are under way in collaboration with the National Cancer Institute (NCI) and the Children's Oncology Group (COG) to evaluate the pharmacokinetics (PK)/pharmacodynamics (PD), safety, and efficacy of chemotherapeutic agents used in children with cancer. The drugs under study are methotrexate, vincristine, daunomycin, and actinomycin-D.

—*Sickle Cell Disease (SCD):* A clinical trial of PK, efficacy, and safety of hydroxyurea to treat infants and young children with SCD is under way, with a planned safety follow-up.

—*Attention Deficit Hyperactivity Disorder:* The NICHD is funding basic and clinical research to evaluate the potential toxicity of methylphenidate.

—*Organophosphate poisonings:* Existing data on the use of pralidoxime for this indication is under review.

- 2007

—*Oncology:* The NICHD consulted with experts in pediatric oncology to discuss the use of 13-cis-retinoic acid for the indication of neuroblastoma and to develop a pediatric formulation for this indication.

—*Methicillin-resistant Staphylococcus aureus* (MRSA) infections: The NICHD consulted with experts in infectious disease to discuss the need for PK, safety, and efficacy studies of clindamycin, doxycycline, tetracycline, and trimethoprim-sulfamethoxazole for the treatment of MRSA infections.

—*Asthma:* The NICHD has pursued potential collaborations with research networks within the NIH that are conducting clinical trials and other research in pediatric asthma, specifically networks supported by the National Heart, Lung, and Blood Institute and the National Institute of Allergy and Infectious Diseases.

—*Hypertension:* A written request for the study of hydrochlorothiazide in hypertension has been received by the NICHD. The NICHD has conducted a third working group meeting with experts in the field of pediatric hypertension to discuss studies needed in this area. Future clinical trials are being considered.

- Other areas of continued or future consideration for study under the BPCA discussed in previous **Federal Register** Notices and/or BPCA scientific meetings include:

—*Obesity:* The NICHD is consulting with experts in the field on the treatment of the metabolic syndrome and obesity-related Type-2 diabetes and hypertension.

—*Counterterrorism research:* The NICHD has developed a working group to discuss the needs in pediatric therapeutics for the treatment of chemical, biologic, radiologic, nuclear, and explosive (CBRNE) exposure. The NICHD is collaborating with the National Institute of Neurological Disorders and Stroke on its Counter-Act initiative to develop new and improved medical counter-measures against chemical threats in children and adults.

—*Influenza and parasitic diseases:* The NICHD held preliminary discussions with international experts on global pediatric pharmacology issues. Influenza and parasitic diseases are potential prototypes for future collaborations.

—*Fragile X syndrome:* The NICHD continues to consult with experts in the field, including the National Institute of Mental Health, to consider selected drugs and clinical outcome measures for evaluation and/or study.

—*Depression:* The NICHD has consulted with experts in the field to consider the approaches and design of safety studies of psychotropic medications in children, including antidepressants and other psychotropic medications.

Throughout 2007 and 2008, the NICHD continued its outreach to pediatric organizations and other NIH Institutes and Centers. The goal of these discussions was specifically to identify current gaps in scientific knowledge regarding research and treatment of pediatric conditions with the ultimate goal of determining approved drugs for which future pediatric studies are needed. Minutes of all working group

meetings conducted under the BPCA can be found on the BPCA Web site listed above.

The ''New'' BPCA

Title V of Public Law 110–85, the Best Pharmaceuticals for Children Act of 2007, was enacted on September 27, 2007, as part of the Food and Drug Administration Amendments Act of 2007.

This legislation, which reauthorizes the BPCA (Section 409I of the Public Health Service Act), extends the provision of additional patent exclusivity for currently on-patent drugs that are being tested for pediatric use. This legislation also extends and expands the research program at the NIH established in the earlier law. The NICHD administers the research program through its Obstetric and Pediatric Pharmacology Branch, working in cooperation with the other NIH Institutes and Centers with significant pediatric research portfolios. Important changes to the 2002 BPCA legislation for the NIH include the following:

- Focus on condition-based approach.
- More flexible funding mechanisms.
- Development of Proposed Pediatric Study Requests (PPSR).
- Feasibility study for the development of a pediatric formulary.

The NICHD will prioritize all therapeutic areas over the upcoming years based on the following considerations:

- Building upon the current foundation established by the 2002 BPCA implementation;
- Evaluating all currently listed drugs and therapeutic areas for feasibility and identification of additional or new scientific and therapeutic gaps;
- Changing the listing process from an individual drug/indication approach to listing needs in pediatric therapeutic areas;
- Determining new areas of need based on consultation with other NIH Institutes and Centers, as well as experts in pediatric therapeutics and the pediatric medical community.

The overall goal of the NIH for implementing the provisions of the BPCA is to improve pediatric therapeutics through scientific advancements and labeling changes that will have an impact on the safe and effective use of drugs in children. This can be accomplished through the following:

- Data gathering

—Using the principles of pharmacoepidemiology research to quantify adverse drug reactions, drug efficacy, and patterns of drug use in large populations to elucidate health services utilization.

—Bringing together multidisciplinary teams to provide input on needs in pediatric therapeutics through outreach to experts in pediatric research in academic institutions; other NIH Institutes and Centers; and pediatric organizations, societies, advocacy groups, and industry.

- Clinical trials

—Phase 1, 2, and 3 clinical trials to increase the knowledge of PK, safety, and efficacy of medicines used in children.

- Basic and translational research

—To inform such areas as developmental pharmacology, pharmacogenomics, and pediatric clinical trial design.

There will be an open scientific meeting annually, starting in 2008, to review and discuss the proposed therapeutic areas, to present progress from ongoing research, and to provide an opportunity for the medical community to provide input into the future therapeutic areas to be studied under the BPCA. Stakeholders will include the NIH, the FDA, and members of the American Academy of Pediatrics, and other pediatric organizations and societies. There will be a report to Congress at least every 3 years starting in 2008. Throughout the year, there will also be smaller group meetings with expert panels within prioritized therapeutic areas under the BPCA. The goals of the working group meetings will be to evaluate and discuss the gaps in scientific knowledge (whether necessary data are available or unavailable) as well as to determine gaps in the treatments of these conditions; for example, to determine what may be needed to enhance the treatment of these conditions in children. These consultations will assist the NICHD in the development of future proposed areas of study encompassing multiple therapeutic categories and/or addressing multiple questions within a therapeutic category.

A scientific prioritization meeting was held in Rockville, Maryland, from June 30 to July 1, 2008, to determine needs in pediatric therapeutics as mandated by the BPCA 2007 legislation. The final BPCA List of Needs in Pediatric Therapeutics, and information on the prioritization process, will be posted on the BPCA Web site *http://bpca.nichd.nih.gov*.

Dated: April 7, 2009.

Raynard S. Kington,

Acting Director, National Institutes of Health.

[FR Doc. E9–8477 Filed 4–13–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2009–0008]

The National Infrastructure Advisory Council

AGENCY: Directorate for National Protection and Programs, Department of Homeland Security.

ACTION: Committee Management; Notice of cancellation for Federal Advisory Committee Meeting.

SUMMARY: The meeting of the National Infrastructure Advisory Council (NIAC) scheduled for Tuesday April 14, 2009 at the J.W. Marriott, 1331 Pennsylvania Avenue, Washington, DC announced in the **Federal Register** on February 17, 2009 (73 FR 7456), will not be held.

FOR FURTHER INFORMATION CONTACT: Contact Matthew Sickbert by phone at 703–235–2888 or by e-mail at *Matthew.Sickbert@associates.dhs.gov*.

Dated: April 9, 2009.

Nancy J. Wong,

Designated Federal Officer for the NIAC.

[FR Doc. E9–8541 Filed 4–10–09; 11:15 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

60-Day Notice of New Information Collection; Form 70–005, ICE Secure Communities Stakeholder ID Assessment Questionnaire; Agency Information Collection Activities: New Information Collection; Comment Request

ACTION: 60-Day Notice of New Information Collection; Form 70–005, ICE Secure Communities Stakeholder ID Assessment Questionnaire.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 15, 2009.