

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://bpcanichd.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]

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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.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20536; (202) 732-6337.

Comments are encouraged and will be accepted for sixty days until June 15, 2009. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* New information collection.

(2) *Title of the Form/Collection:* ICE Secure Communities Stakeholder ID Assessment Questionnaire.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form 70-005, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households, Business or other non-profit. The information collected on the Form 70-005 is necessary for U.S. Immigration and Customs Enforcement (ICE) to provide immigration bond obligors a standardized method to notify ICE of address updates. Upon receipt of the formatted information records will then be updated to ensure accurate service of correspondence between ICE and the obligor.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,000 responses at 10 minutes (0.1667 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 166.7 annual burden hours.

Comments and/or questions; requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20536; (202) 732-6337.

Dated: April 8, 2009.

Joseph M. Gerhart,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E9-8391 Filed 4-13-09; 8:45 am]

BILLING CODE 9111-28-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Change of Use for the Oak Shores Recreation Area at Lake Berryessa, Napa County, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of change in use of public access.

SUMMARY: The Bureau of Reclamation's Central California Area Office (CCAO) at Lake Berryessa will temporarily change public use at Oak Shores Day Use Area. After 50 years, concession contracts have expired and recreational opportunities provided at four closed resorts are no longer available. Until such time as new contracts can be awarded, Reclamation will provide a change from day use to overnight camping at this area. The North End of Oak Shores will be converted from day use only to overnight camping with up to 100 sites. Camping will be considered semi-primitive and will provide potable water spigots, restroom facilities, fire rings, picnic tables and some shade shelters. This change in use will serve to enhance public safety, provide additional public recreational services while providing for and protection of cultural and natural resources.

DATES: *Effective Dates:* The change of use will become effective May 22, 2009 and continue indefinitely until new contracts can be awarded and the new concessioner can begin to provide recreational services.

ADDRESSES: A map is available for review at Reclamation's Lake Berryessa Visitor Center, located at 5520 Knoxville Rd, Napa, California 94558. The map may be viewed between the hours of 10 a.m. and 4 p.m. daily. A copy of the map may be requested from above address, attention: Lake Berryessa Change of Use Map Request.

FOR FURTHER INFORMATION CONTACT:

Reclamation, Mid-Pacific Region Public Affairs Office, at 916-978-5100 or Reclamation, Lake Berryessa Recreation Resources Branch, 707-966-2111. Written comments will be accepted regarding this change of use through May 14, 2009. Please send written comments to: Bureau of Reclamation, Attn: Janet Rogers, 5520 Knoxville Rd., Napa, California; Fax: 707-966-0409, E-mail: jrogers@usbr.gov.

SUPPLEMENTARY INFORMATION: This action is being taken under 43 CFR part 423 to provide recreational services to the public, provide public safety and prevent additional resource degradation. Reclamation will change public use of Oak Shores. Presently Oak Shores is being used for day use; picnics, fishing, wildlife viewing, and swimming. By not providing designated camping, additional resource degradation at non-designated sites would occur.

The south side of Oak Shores will remain open for day use and the north side will be sectioned off to provide for the campsites. Camping at Oak Shores will be available for up to fourteen days only during any period of 30 consecutive days, as required by 43 CFR part 423.33.

Reclamation will develop the campgrounds and offer an interim contract to a concessioner for operation of the campgrounds. Security will be provided by the concessioner. A reservation system will be required and fees will be charged based on comparable fees to other areas in a 100 mile radius of Lake Berryessa. The public will be notified of the changes through signage, newspaper press releases and Web site postings.

This order is posted in accordance with 43 CFR part 423.60. Violation of this prohibition or any prohibition listed in 43 CFR part 423 is punishable by fine or imprisonment for not more than six months or both.

Dated: April 7, 2009.

Michael R. Finnegan,

Area Manager, Central California Area Office.

[FR Doc. E9-8468 Filed 4-13-09; 8:45 am]

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