

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.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Virology Studies.

*Date:* August 21, 2003.

*Time:* 1 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Robert Freund, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7808, Bethesda, MD 20892, (301) 435-1050, [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

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(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: August 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03-20554 Filed 8-12-03; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### List of Additional Drugs for Which Pediatric Studies Are Needed

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH) is providing notice of a "List of Additional Drugs for Which Pediatric Studies Are Needed." This listing extends the initial list published in the **Federal Register** on January 21, 2003 (Volume 68, Number 13, pages 2789-2790). The NIH has developed the list in consultation with the Food and Drug Administration (FDA) and pediatric experts, as mandated by section 409I of the Best Pharmaceuticals for Children Act (BPCA), Public Law 107-109. This list prioritizes additional drugs most in need of study for use by children to ensure their safety and efficacy. It will be updated regularly until the Act expires on October 1, 2007.

**DATES:** This list is effective upon publication.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donald Mattison, National Institute of Child Health and Human Development,

6100 Executive Boulevard, Room 4B-100, Rockville, MD, 20892, e-mail [BestPharmaceuticals@mail.nih.gov](mailto:BestPharmaceuticals@mail.nih.gov), telephone 301-496-5097 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The NIH is providing notice of a "List of Additional Drugs for Which Pediatric Studies Are Needed." On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish on at least an annual basis a list of approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); or (2) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; or (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider, for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary.

In developing this addition to the initial list published on January 21, 2003, the NIH consulted with the FDA, the American Academy of Pediatrics, the United States Pharmacopoeia and other experts in pediatric research. A preliminary list of certain off-patent drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

Following are the additional drugs for which pediatric studies are most urgently needed:

Ampicillin/sulbactam.

Diazoxide.  
Isoflurane.  
Lindane.  
Meropenem.  
Metoclopramide.  
Piperacillin/tazobactam.  
Promethazine.

Dated: August 4, 2003.

**Elias A. Zerhouni,**

*Director, National Institutes of Health.*

[FR Doc. 03-20558 Filed 8-12-03; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[Program Announcement No. ACF-HHS-ORR-07-28-2003]**

#### ORR Announcement for Services to Recently Arrived Refugees

**AGENCY:** Office of Refugee Resettlement (ORR) Administration for Children and Families, HHS.

**ACTION:** Notice of an additional closing date for the ORR Standing Announcement for Services to Recently Arrived Refugees: Category One—Preferred Communities, published in the **Federal Register** on May 9, 2001 (66 FR 23705).

**CFDA #:** The Catalog of Federal Domestic Assistance is 93.576.

**SUMMARY:** The current Standing Announcement for Services to Recently Arrived Refugees posted on May 9, 2001 includes an application deadline of February 28. This notice announces an additional, one-time closing date for Category One of this standing announcement.

**ELIGIBILITY:** As specified in the announcement posted on May 9, 2001, eligible applicants are agencies that currently resettle refugees under a Reception and Placement Cooperative Agreement with the Department of State or with the Department of Justice.

**SUMMARY:** For the past two years, refugee arrival numbers have been low, and agency staff has been reduced. With the arrival of the Somali Bantu, resettlement staff will be presented with many challenges, and local services will need to be enhanced. Through this additional closing date, ORR intends to provide resources to meet the needs of the Somali Bantu.

**DATES:** The closing date for applications is September 12, 2003. Please note that all applications must be received (as opposed to postmarked) in ACF by this date or they will be considered late. Due