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.

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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

Ampicillin/sulbactam.
Diazoxide.
Isoflurane.
Lindane.
Lumopenem.
Metoclopramide.
Piperacillin/tazobactam.
Promethazine.

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.