ATTACHMENT 4

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7824, Bethesda, MD 20892, (301) 435–1153, *revzina@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Neurotoxicology and Alcohol Study Section.

Date: June 8–9, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington Embassy Row, 2015 Massachusetts Ave., NW., Washington, DC 20036.

Contact Person: Joseph G. Rudolph, Ph.D, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–435–2212, *josephru@csr.nih.gov.*

Name of Committee: Hematology Integrated Review Group, Hematopoiesis Study Section.

Date: June 8–9, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert T. Su, Ph.D, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892, (301) 435–1195, *sur@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section.

Date: June 8–9, 2006.

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

Agenda: To review and evaluate grant applications.

Place: City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: Tera Bounds, PhD, Scientific Review Administrator, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 3015–D, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics C Study Section.

Date: June 8–9, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1111 30th Street, NW., Washington, DC 20007.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, (301) 435–4511, *whitmarshb@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics A Study Section.

Date: June 8–9, 2006.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

Contact Person: Michael M. Sveda, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7842, Bethesda, MD 20892, (301) 435–3565, *svedam@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Community Influences on Health Behavior.

Date: June 8–9, 2006.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Ellen K. Schwartz, EDD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3168, MSC 7770, Bethesda, MD 20892, (301) 435–0681, *schwarte@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Enabling Bioanalytical and Biophysical Technologies Study Section.

Date: June 8–9, 2006.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Noni Byrnes, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4180, MSC 7806, Bethesda, MD 20892, (301) 435–1217, *byrnesn@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry B Study Section.

Date: June 8–9, 2006.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Mike Radtke, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, (301) 435–1728, *radtkem@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Biostatistical Methods and Research Design Study Section.

Date: June 9, 2006.

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

Agenda: To review and evaluate grant applications.

Place: George Washington University Inn, 824 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: Ann Hardy, DRPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, (301) 435–0695, *hardyan@csr.nih.gov.*

(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, 83.892, 93.893, National Institutes of Health, HHS)

Dated: April 13, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3880 Filed 4–24–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Office of Chemical Nomination and Selection; Announcement of and Request for Public Comment on Toxicological Study Nominations to the NTP; Clarification

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Clarification.

SUMMARY: The NTP is issuing a clarification of a **Federal Register** notice published on April 11, 2006 (Volume 71, Number 69, pages 18341–18344), because a table summarizing the toxicological study nominations contains several misaligned columns and rows. A correct version of the table is available on the NTP Web site at *http://ntp.niehs.nih.gov/go/21134* or by contacting Dr. Scott Masten (see **ADDRESSES** below).

ADDRESSES: Correspondence should be addressed to Dr. Scott A. Masten, Director, Office of Chemical Nomination and Selection, NIEHS/NTP, 111 T.W. Alexander Drive, P.O. Box 12233, Research Triangle Park, North Carolina 27709; telephone: 919–541–5710; FAX: 919–541–3647; e-mail: *masten@niehs.nih.gov.*

Dated: April 12, 2006.

David Schwartz,

Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E6–6121 Filed 4–24–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

List of Drugs for Which Pediatric Studies Are Needed

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is providing notice of the

"List of Drugs for Which Pediatric Studies Are Needed." The NIH developed the list in consultation with the Food and Drug Administration (FDA) and pediatric experts, as mandated by the Best Pharmaceuticals for Children Act. This list prioritizes certain drugs most in need of study for use by children to ensure their safety and efficacy. The NIH will update the list at least annually until the Act expires on October 1, 2007.

DATES: The list is effective upon publication.

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata, 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: The NIH is providing notice of the "List of Drugs for Which Pediatric Studies Are Needed," as authorized under Section 3, Pub. L. 107–109 (42 U.S.C. 409I). On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that not later than one year after the date of enactment, the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain 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)); (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; (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. For this year, we are providing an update on all of the drugs listed since the enactment of BPCA and a brief status report on each of the drugs (see Table 1).

TABLE 1.—CURRENT STATUS OF DRUGS THAT HAVE BEEN LISTED BY NIH (NICHD) FOR BPCA

Drug	Indication	Listing	Patent status	Written request/RFP	Clinical trial primary site	Current status and/or clinical trial design
Acyclovir*	Herpetic infections	2005	On-patent	FDA	N/A	Recommended for systematic review for potential re-labeling based on published literature.
Ampicillin	Infection	2004	Off-patent	NICHD	N/A	Awaiting systematic literature review for the development of RFP.
Ampicillin/sulbactam	Infection	2003	Off-patent	FDA	N/A	Inactive. Being reconsidered due to feasibility issues.
Azithromycin (IV)	Prevention of bronchopulmonary dysplasia (BPD) in neonates colonized with Ureaplasma urealyticum.	2003	Off-patent	NICHD	N/A	PK, safety, efficacy, tolerability studies proposed. Currently reviewing scientific issues.
Azithromycin (PO)	Prevention treatment of Chlamydia conjunctivitis and pneumonia.	2003	Off-patent	NICHD	N/A	Inactive for this indication. Initial Studies proposed difficult to conduct due to feasibility issues. RFP released but no responses received. Indication being reconsidered.
Baclofen*	Oral treatment of spasticity from cerebral palsy.	2003	On-patent	FNIH, NICHD.	Negotiations ongoing	Plan is for Pharmacokinetics, safety and efficacy studies. FNIH considering funding.
Bumetanide	Diuresis	2003	Off-patent	FDA	N/A	Has been recommended for consultation with scientific community concerning diagnosis and treatment of pediatric hypertension, and the role of diuretics in treatment.
Bupropion*	Treatment of Depression.	2004	On-patent	FNIH, NICHD.	N/A	Recommended for systematic review and consultation with scientific community. Written Request referred to FNIH.
Bupropion*	Treatment for smoking cessation.	2004	On-patent	FNIH, NICHD.	N/A	Written Request referred to FNIH.

TABLE 1.—CURRENT STATUS OF DRUGS THAT HAVE BEEN LISTED BY NIH (NICHD) FOR BPCA—Continued

Drug	Indication	Listing	Patent status	Written request/RFP	Clinical trial primary site	Current status and/or clinical trial design
Clonidine	Autism	2005	Off-patent	FDA	N/A	Data gathering in process. Indication being reconsidered due to feasibility issues.
Clonidine	Attention deficit disorder.	2005	Off-patent	FDA	N/A	Recommended for systematic review and consultation with scientific community. Reconsidered for listing for 2006 under condition-based approach.
Cyclosporine	Cardiac transplant rejection.	2005	Off-patent	FDA	N/A	Recommended for systematic review and consultation with scientific community to discuss feasibility and study design in cardiac transplant patients.
Dactinomycin	Cancer	2004	Off-patent	NICHD	NICHD Partnership with NCI/Children's Oncology Group.	Clinical studies being conducted by Children's Oncology Group in conjunction with NCI to better define safety, efficacy, PK.
Daunomycin	Cancer	2006	Off-patent	FDA	N/A	WR in process.
Dexrazoxane*	Prophylaxis from cardiotoxicity of doxorubicin.	2005	On-patent	FNIH, NICHD.	N/A	WR referred to FNIH.
Diazoxide	Hypoglycemia	2003	Off-patent	FDA	N/A	Inactive. Being considered for labeling based on literature review.
Dobutamine	Hypotension, low cardiac output in neonates.	2003	Off-patent	FDA	N/A	Inactive due to issues with feasibility and clinical trial design.
Dopamine	Hypotension, low cardiac output in neonates.	2003	Off-patent	FDA	N/A	Inactive due to issues with feasibility and clinical trial design.
Eletriptan*	Migraine headaches in adolescents.	2005	On-patent	FNIH, NICHD.	N/A	WR referred to FNIH.
Ethambutol	Tuberculosis	2005	Off-patent	FDA	N/A	Data gathering in process.
Flecainide	Ventricular arrhythmia.	2005	Off-patent	FDA	N/A	Recommended for systematic review and consultation with scientific community to determine feasibility and study design.
Furosemide	Diuresis	2003	Off-patent	FDA	N/A	Recommend consultation with scientific community concerning diagnosis and treatment of pediatric hypertension, and the role of diuretics in treatment.
Griseofulvin	Tinea capitis	2005	Off-patent	NICHD	N/A	Development of RFP in progress.
Heparin	Anticoagulation	2003	Off-patent	FDA		Already labeled for patients ≥ 1 kg.
Hydrochlorothiazide	Hypertension	2005	Off-patent	FDA	N/A	Recommend consultation with scientific community concerning diagnosis and treatment of pediatric hypertension, and the role of diuretics in treatment.
Hydrocortisone valerate ointment and cream*.	Dermatitis	2005	On-patent	FDA	N/A	Inactive.
Hydroxychloroquine	Connective tissue disorders.	2005	Off-patent	FDA	N/A	WR in process.
Hydroxyurea*	Sickle Cell Disease	2006	On-patent	FNIH, NICHD.	NICHD Partnership with NHLBI.	PK, efficacy and safety studies under way. FNIH considering funding.

TABLE 1.—CURRENT STATUS OF DRUGS THAT HAVE BEEN LISTED BY NIH (NICHD) FOR BPCA—Continued

Drug	Indication	Listing	Patent status	Written request/RFP	Clinical trial primary site	Current status and/or clinical trial design
Isofluorane	Maintenance of general anesthesia.	2003	Off-patent	FDA	N/A	Awaiting results of Ketamine preclinical study and results to be extrapolated.
Ivermectin	Scabies	2005	Off-patent	FDA	N/A	Formulation issues may preclude study.
Ketamine	Sedation	2004	Off-patent	FDA	NICHD Partnership with NCTR, FDA.	Preclinical toxicology studies under way. Clinical studies will not be designed until the preclinical studies are completed.
Lindane	Second line treatment of scabies.	2003	Off-patent	FDA	N/A	WR accepted by NDA holder.
Lithium	Treatment of mania in bipolar disorder.	2003	Off-patent	NICHD	Case Western Reserve University.	PK, safety, efficacy, and tolerability studies to be performed.
Lorazepam	Treatment of Status Epilepticus.	2003	Off-patent	NICHD	Children's National Medical Center.	PK, efficacy, and safety. Participants are currently being enrolled in PK study. Feasibility issues with efficacy trial.
Lorazepam	Sedation in the intensive care unit for children on respirators.	2003	Off-patent	NICHD	Case Western Reserve University.	Pharmacokinetics, safety, efficacy by randomized double-blind active comparator study. Participants are currently being enrolled.
Meropenem	Infection	2003	Off-patent	NICHD	N/A	Currently in negotiations.
Methadone	Neonates with opioid withdrawal.	2005	Off-patent	FDA	N/A	Data gathering in process.
Methotrexate	Cancer	2006	Off-patent	FDA	N/A	WR in process.
Metoclopramide*	Gastro-esophageal reflux.	2003	On-patent	NICHD	N/A	Inactive due to change in patent status after listing.
Metolazone	Diuresis	2004	Off-patent	FDA	N/A	Recommend consultation with scientific community concerning diagnosis and treatment of pediatric hypertension and the role of diuretics in treatment.
Morphine*	Analgesia	2004	On-patent	FNIH, NICHD.	Children's National Medical Center.	Basic science studies are needed to determine the developmental expression and function of opioid receptors. FNIH considering funding. Grant awarded by NICHD in 2005 for study in neonates.
Piperacillin/tazobactam.	Infection	2003	Off-patent	FDA	N/A	Inactive. Being reconsidered due to feasibility issues.
Pralidoxime	Organophosphate Poisoning.	2006	Off-patent	Pending	N/A	Recommended for systemic literature review.
Promethazine	Nausea and vomiting	2003	Off-patent	FDA	N/A	Inactive. Under consideration for removal from list due to current black boxed warning.
Rifampin	Methicillin-resistant Staphylococcus aureus endocarditis.	2003	Off-patent	NICHD	N/A	Inactive. Frequency of condition being reviewed.
Rifampin	Central nervous system shunt infection.	2003	Off-patent	NICHD	N/A	Inactive. Frequency of condition being reviewed.
Sevelamer*	Hyperphosphatemia in chronic renal failure.	2005	On-patent	FNIH, NICHD.	N/A	Written Request referred to FNIH.

TABLE 1.—CURRENT STATUS OF DRUGS THAT HAVE BEEN LISTED BY NIH (NICHD) FOR BPCA—Continued

Drug	Indication	Listing	Patent status	Written request/RFP	Clinical trial primary site	Current status and/or clinical trial design
Sodium nitroprusside	Control of blood pressure.	2003	Off-patent	NICHD	Duke and Stanford Universities.	Pharmacokinetics, safety, efficacy by randomized double-blind parallel group study design. Participants are currently being enrolled.
Spironolactone	Diuresis	2003	Off-patent	FDA	N/A	Recommend consultation with scientific community concerning diagnosis and treatment of pediatric hypertension and the role of diuretics in treatment.
Vincristine	Cancer	2004	Off-patent	NICHD	NICHD Partnership with NCI/Children's Oncology Group.	Clinical studies being conducted by Children's Oncology Group with National Cancer Institute to better define safety, efficacy, and PK.
Zonisamide*	Partial Seizures	2005	On-patent	FNIH, NICHD.	N/A	Written Request referred to FNIH.

Key: Drug is the generic name. Indication summarizes the indication or condition for which the drug is to be tested. Listing notes the year in which the drug was added to the list for testing. Patent Status is the on- or off-patent status of the drug. WR indicates a Written Request has been issued by the FDA and denotes where the request for and the processing of information currently resides (FDA, Foundation for NIH (FNIH) or NIH). Request for Proposals (RFP) indicates the RFP was published by NICHD and its current status. Clinical Trial Primary Site identifies the institution that has received the contract and has designed and implemented the preclinical or clinical protocol. Clinical Trial Design indicates in general terms the format of the proposed or actual preclinical or clinical trials and the phases of drug development being conducted. N/A refers to a process that is not applicable to a particular drug at this time. NHLBI is the National Heart, Lung, and Blood Institute; NCI is the National Cancer Institute; NIEHS is the National Institute of Environmental Health Sciences; NIMH is the National Institute of Mental Health; and NCTR is the National Center for Toxicological Research, part of the FDA.

*Indicates that a drug is currently on-patent and will be studied under a different funding mechanism than the off-patent process as described in the BPCA Legislation of 2002. For an on-patent drug, if the manufacturer has denied or failed to respond to the WR issued by the FDA in 120 days, the FDA refers the drug to the FNIH and requests that it be considered for FNIH support of pediatric studies. These drugs are also discussed at the annual scientific listing meetings.

As previously stated, NICHD and the FDA have reviewed the progress of the drugs currently listed under BPCA in addition to a review of the entire listing process since its inception. There are drugs listed that are currently considered inactive or are being reconsidered due to multiple factors. Many of the factors for reconsideration are based on feasibility issues related to clinical trial design and the overall conduct of a study with that particular drug and/or indication—such as frequency of condition, statistical power, and safety. A drug may also be considered inactive if there has been a change in patent status since its original listing. These drugs will continue to be reevaluated throughout the year and an update will be provided no later than January 2007.

Upon review of the BPCA listing process and based on our goal of improving pediatric therapeutics, NIH and FDA have decided to change our listing system to a therapeutic class-based approach. We believe that this approach will allow us to compare drugs within a therapeutic class (on- and off-patent) and give a broader description for the availability and use of these drugs in children. This will also allow us to obtain focused expertise in therapeutic areas that will subsequently give us more insight into feasibility and study designs. We drafted and categorized a preliminary list of drugs for the 2006 Priority List based on the newly developed condition-based approach in an effort to identify areas in pediatrics that may contain gaps in knowledge in the area of therapeutic options. In developing this list, the NIH consulted with the FDA and experts in pediatric research and practice. The following are the conditions and the drugs discussed in our November 8–9, 2005, scientific meeting with experts in pediatric research and determined to need more scientific evidence before studies can be conducted in children: Attention Deficit and Hyperactivity Disorder (ADHD), Hypertension, Parasitic Diseases, Influenza, Cancer, Poisonings, and Sickle Cell Anemia. The drugs thought to be effective for treatment in each of these conditions were then prioritized based on the potential for providing a health benefit in the general pediatric population.

ADHD was identified as a therapeutic area of interest because of its tremendous impact on the use of psychotropic medications in children—remaining the most commonly diagnosed behavioral disorder of childhood. Clonidine and Guanfacine were discussed as off-patent drugs that require further information in children. We determined that we need further discussion with the primary care and mental health communities to determine if studies of these agents are warranted for the treatment of ADHD or if the primary use of these agents is as adjunctive agents because of their sedative properties. In 2005, NICHD learned of a published report in *Cancer Letters* discussing possible cytogenetic effects in children treated with Methylphenidate (*Cytogenetic effects in children treated with methylphenidate*, El-Zein, R. et al., *Cancer Letters* xx (2005), 1–8.). NICHD developed a partnership with the National Institute of Environmental Health Sciences, the National Institute of Mental Health, the National Center for Toxicology Research, and the FDA to further evaluate this finding.

Hypertension was identified as a therapeutic area of interest due to the recent "Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents," published in *Pediatrics* in 2004, which identified a need to determine a treatment strategy for high blood pressure in children, especially

with the increasing epidemic of obesity and obesity-related diseases in this country. The therapeutic drugs class of Diuretics (Bumetanide, Furosemide, Hydrochlorothiazide, Spironolactone) were discussed as off-patent drugs that require further information in children. It was determined that we need further discussion with the pediatric experts involved in the development of the "Fourth Report" to determine if, and how, this particular class of drugs is used in primary pediatric hypertension and how a clinical study might be structured to address the complex issues that have recently arisen, such as obesity-related hypertension, in the diagnosis and treatment of this disease.

Parasitic Diseases was identified as a therapeutic area of interest due to the tremendous impact on morbidity and mortality that these diseases have in children worldwide. Albendazole and Mebendazole were discussed as off-patent drugs that require further information in children. It was determined that we need to consult with domestic (Centers for Disease Control and Prevention) and foreign sources (World Health Organization) and other areas where these agents are predominantly monitored and used to obtain safety information. It was also determined that a liquid formulation of Albendazole would be advantageous for children of developing countries, in whom these diseases occur more often.

Influenza was identified as a therapeutic area of interest because of the emerging threat of pandemic flu and the lack of dosing and efficacy data in our most vulnerable pediatric population—children less than 1 year of age. Amantidine and Rimantidine were discussed as off-patent drugs that require further information in children. It was determined that we need more information on the effectiveness of these drugs to provide additional insight into the use of these agents in the population of children less than 1 year of age.

Cancer has been identified as an ongoing therapeutic area of interest because of the extensive morbidity and mortality that this disease continues to exhibit in pediatric patients of all ages.

Poisoning was identified as a therapeutic area of interest due to the fact that injuries and poisonings remain as one of the top 5 conditions that lead to the highest morbidity and mortality in young children and adolescents.

Sickle Cell Anemia was identified as a therapeutic area of interest because of the extensive morbidity caused by, and paucity of treatment options for, this disease.

The following are the conditions and drugs discussed in our November 8–9, 2005, scientific meeting with experts in pediatric research. We will add these conditions and drugs to the 2006 priority list for which pediatric studies are most urgently needed, along with their indications for use:

Treatment of Pediatric Cancers: Methotrexate and Daunomycin

There is an urgent need for information regarding the pharmacokinetics and toxicity of daunomycin in obese children. There is an urgent need to evaluate the neurotoxicity and long-term cognitive outcomes of children receiving methotrexate.

Treatment of Sickle Cell Anemia: Hydroxyurea

There is an urgent need for further pharmacokinetic and long-term safety data in the use of this drug in children with sickle cell anemia.

Treatment of Organophosphate Poisoning: Pralidoxime

There is an urgent need for further dosing information of the use of this drug in children.

For the coming year, NICHD is planning a series of discussions with experts in the field of pediatric cancers (NCI/COG), pediatric infectious diseases, emergency care in pediatrics (PECARN), pediatric-based research networks (PBRN), pediatric hypertension, and pediatric psychiatry, in addition to our ongoing discussions with the other NIH Institutes and Centers. The goal of these discussions will be to specifically identify current gaps in scientific knowledge regarding research and treatment of these various pediatric conditions, with the ultimate goal of determining future approved drugs for which pediatric studies are needed. NICHD will continue scientific discussions and planning throughout 2006 and will provide an update in January 2007.

Dated: April 11, 2006.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. E6–6122 Filed 4–24–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–23665]

Collection of Information Under Review by Office of Management and Budget (OMB): 1625–0009, 1625–0014, 1625–0038, and 1625–0039

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard has forwarded four Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) for review and comment. The ICRs are as follows: (1) 1625–0009, Oil Record Book for Ships; (2) 1625–0014, Request for Designation and Exemption of Oceanographic Research Vessels; (3) 1625–0038; Plan Approval and Records for Tank, Passenger, Cargo and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels, Oceanographic Research Vessels and Electrical Engineering—46 CFR Subchapters D, H, I, I–A, J, R, and U; and (4) 1625–0039, Declaration of Inspection Before Transfer of Liquid Cargo in Bulk. Our ICRs describe the information we seek to collect from the public. Review and comment by OIRA ensures that we impose only paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before May 25, 2006.

ADDRESSES: To make sure that your comments and related material do not reach the docket [USCG–2006–23665] or OIRA more than once, please submit them by only one of the following means:

(1)(a) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. (b) By mail to OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(2)(a) By delivery to room PL–401 at the address given in paragraph (1)(a) above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329. (b) By delivery to OIRA, at the address given in paragraph (1)(b) above, to the attention of the Desk Officer for the Coast Guard.

(3) By fax to (a) the Facility at (202) 493–2298 and (b) OIRA at (202) 395–