

print and online materials, outreach activities, and messages to maximize their impact and usefulness.

OCPL wishes to continue to carry out formative research to further understand the knowledge, attitudes, and behaviors of its core constituent groups: members of the general public, researchers, and providers of both conventional and CAM health care. In addition, it seeks to test newly formulated messages and identify barriers and impediments to the effective communication of those messages. With this audience research, OCPL will carry out pretesting of audience responses to NCCAM's fact sheets, Web content, and other materials and messages.

Clearance is also requested to continue to carry out evaluative research on existing materials and messages, as part of OCPL's ongoing effort to develop a comprehensive program of testing and evaluation of all of its communications strategies. This evaluative research will include pilot testing of recently developed messages and information products such as fact sheets and brochures. It will also address the need to evaluate the processes by which new materials and messages were developed, the effectiveness of an outreach or the extent to which behaviors were changed by the message, and the impact of a message on health knowledge and behaviors.

The tools to collect this information have been selected to minimize burden on NCCAM's audiences, produce or refine messages that have the greatest potential to influence target audience attitudes and behavior in a positive manner, and to use Government resources efficiently. They may include individual in-depth interviews, focus group interviews, intercept interviews, self-administered questionnaires, gatekeeper reviews, and omnibus surveys.

The data will enhance OCPL's understanding of (1) the unique information needs and distinct health-information-seeking behaviors of its core constituencies, and (2) the segments within these constituencies with special information needs (for example, among the general public these segments include cancer patients, the chronically ill, minority and ethnic populations, the elderly, users of dietary supplements, and patients integrating complementary therapies with conventional medical treatments).

Frequency of Response: On occasion.

Affected Public: Individuals and households; non-profit institutions; Federal Government; State, Local, or Tribal Government.

Type of Respondents: Adult patients; members of the public; health care professionals; organizational representations. The annual reporting burden is as follows.

Estimated Number of Respondents: 2,440;

Estimated Number of Responses per Respondent: 1;

Average Burden Hours per Response: 0.29; and

Estimated Total Burden Hours Requested: 2,137.5 for the 3-year clearance period (approximately 712.5 hours annually). The annualized cost to respondents is estimated at \$21,333. There are no Capital Costs, Operating Costs, or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumption used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Christy Thomsen, Director, Office of Communications and Public Liaison, NCCAM, 31 Center Drive, Room 2B11, Bethesda, MD 20892, or fax your request to 301-402-4741, or e-mail thomsenc@mail.nih.gov. Ms. Thomsen can be contacted by telephone at 301-451-8876.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 20, 2007.

Christy Thomsen,

Director, Office of Communications and Public Liaison, National Center for Complementary and Alternative Medicine, National Institutes of Health.

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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 "Priority List of Drugs for Which Pediatric Studies Are Needed." The NIH develops 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 that are 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, Public Law 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 and a summary of the progress made by the prioritization working group from last year's notice until now, as well as a summary of the annual scientific prioritization meeting held with pediatric experts on December 5–6, 2006.

We have updated the complete list of drugs, listed previously in the April 2006 **Federal Register** notice, and post it on the BPCA Web site <http://bpca.nichd.nih.gov/index.cfm>. We will continue to reevaluate this list throughout the year and will provide updates as required, based upon the reauthorization of the BPCA.

In 2005, and with the suggestion of pediatric experts, NIH changed the listing system from a focus on individual off-patent drugs to a therapeutic class-based approach. Pediatric experts indicated that this approach will allow us to compare drugs within a therapeutic class (on and off patent) and give a broader description of the use of these drugs in children. This approach will also allow us to obtain focused expertise in therapeutic areas that will subsequently give us more insight into scientific gaps in treatments of the proposed conditions, as well as feasibility and study designs. Based on expert opinion obtained throughout the year as part of our regular outreach program, a preliminary list of conditions and suggested drugs was drafted and categorized for the 2007 prioritization based on this approach.

The following are the conditions and the drugs discussed in our December 5–6, 2006 scientific meeting with experts in pediatric research: Infectious Diseases, with a focus on Methicillin-resistant *Staphylococcus aureus* (MRSA) infections; Pediatric Cancer, specifically Neuroblastoma; Neonatal Pain; and Asthma. The gaps in scientific knowledge as well as specific drugs thought to be effective for treatment in each of these conditions were then discussed based on off-patent status, gaps in pediatric labeling, and the potential for providing a health benefit in the general pediatric population. We also provided updates on our current

work in the areas of Pediatric Hypertension, Sickle Cell Anemia, and Attention Deficit Hyperactivity Disorder during this meeting. There was also a brief discussion on future areas of consideration, pending the reauthorization of the BPCA, that include topics such as childhood obesity, counter-terrorism research, and Fragile X Syndrome.

Following below are the conditions and drugs we discussed in the December 5–6, 2006, scientific meeting with experts in pediatric research. We will add these conditions and drugs, and their indications for use, to the Priority List for 2007 for which pediatric studies are most urgently needed.

Treatment of Pediatric Cancers: 13-Cis-Retinoic Acid

There is a need for information regarding the pharmacokinetics, safety, and efficacy of 13-Cis-Retinoic Acid in the treatment of neuroblastoma.

Treatment of Pediatric MRSA: Clindamycin, Tetracycline, Doxycycline and Trimethoprim-Sulfamethoxazole

There is a need for further pharmacokinetic and safety data in the use of these drugs to treat children with MRSA infections.

In addition to the above conditions and their associated drugs for consideration, the following are conditions that have been identified as needing improvements in the treatment strategies and/or assessments in pediatrics.

Pediatric Hypertension

Data from the medical literature, clinical trials, and experience were presented and discussed by experts in the field of Pediatric Hypertension. Gaps in knowledge in this field include standardization of blood pressure measurements in children as well as the sequence of drugs for hypertension treatment in children.

Asthma

Data from the medical literature, clinical trials, and experience were presented and discussed by experts in the field of Pediatric Asthma. Gaps in knowledge in this field include gaps in measuring efficacy and safety of treatments and drug delivery systems, especially in young children. There is also a need for the development of new tools to identify symptom measures, pulmonary function tests, biomarkers, and genetics.

Neonatal Research

There are many areas in the field of neonatal medicine that can benefit from

advances in neonatal research. Such gaps in research include areas such as determining feasibility of studying specific drugs in low-birth-weight infants based on current use; the development of novel study designs that take into account the small number of patients available due to either ethical limitations and/or feasibility issues; and the performance of clinical studies in areas such as the treatment of pain, neonatal seizures, and bronchopulmonary dysplasia, based on templates that are being developed by experts in research such as the working groups of the Newborn Drug Development Initiative.

For the coming year, NICHD is planning a series of discussions with experts in the fields listed above and plans to identify and work with experts in these respective fields along with our continuing discussions with the other NIH Institutes and Centers. The goal of all 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.

Dated: March 15, 2007.

Raynard S. Kington,

Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing