

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Pediatric Pharmaceutical Usage—Request for Comment

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH) is interested in identifying and obtaining information on prescription drug use in pediatric and young adult populations, neonates to age 18. This notice is a request for information and not a Request for Proposal (RFP) or solicitation.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2002, President George W. Bush signed into law the Best Pharmaceuticals for Children Act (BPCA), Pub. L. 107-109. The BPCA mandates that the NIH, in consultation with the Food and Drug Administration (FDA) and experts in pediatric research, 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 must be an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); or (2) there must be 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 must be no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there must be a referral for inclusion on the list under section 505A(d)(4)(c) of the Federal Food, Drug, and Cosmetic Act; and, in the case of drugs referred to in criteria (1), (2), or (3), additional studies must be 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.

Recently, NIH, in consultation with the FDA and other experts in

pharmaceutical use and pediatric research, developed a preliminary list of certain off-patent drugs that it 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. This initial listing was published in the **Federal Register** on January 21, 2003 (68 FR 2789).

Current Data Needs

To further support the development of a list of drugs that need studies in pediatric populations, the NICHD is seeking information on current usage, in terms of frequency, prevalence, duration, indication and (possibly) toxicity, of drugs in pediatric populations. The NICHD will use the available databases and analyses to prioritize drugs to be further tested in these populations.

ADDRESSES: Any organization with data on prescriptions written and filled for pediatric populations is requested to contact NICHD with a complete statement of what is available and any associated costs for access to the database and analyses of the data. Specifically, organizations with such data, or expertise analyzing such data, should contact Tamar Lasky, Ph.D., NICHD, Mailstop 7510, 6100 Executive Boulevard, Rockville, MD 20892, 301-594-8670, bestpharmaceuticals@mail.nih.gov.

Due Date: Organizations providing information on prescriptions written and filled for pediatric populations should contact Dr. Tamar Lasky on or before November 18, 2003.

Dated: September 11, 2003.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Immigration and Customs Enforcement

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review; Memorandum of Understanding to Participate in an Employment Eligibility Confirmation Pilot Program (OMB-18).

The Department of Homeland Security (DHS), Bureau of Immigration

and Customs Enforcement, has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until November 18, 2003.

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:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Memorandum of Understanding to Participate in an Employment Eligibility Confirmation Pilot Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (File No. OMB-18). SAVE Program, Bureau of Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Employers electing to participate in a pilot will execute a Memorandum of Understanding with the Immigration and Naturalization Service and the Social Security Administration (if applicable), that provides the specific terms and conditions governing the pilot and company information for each site that will be performing employment verification queries.