

Prevention (CDC). Global polio eradication is anticipated within the next few years. The only sources of wild polio virus will be in biomedical laboratories. Prevention of inadvertent transmission of polio viruses from the laboratory to the community is crucial.

The first step toward prevention is a national survey of all biomedical laboratories. The survey will alert laboratories to the impending eradication of polio, encourage the disposition of all unneeded wild polio virus infectious and potentially infectious materials, and establish a national inventory of laboratories retaining such materials. Laboratories on the inventory will be kept informed

of polio eradication progress and notified, when necessary, to implement bio-safety requirements appropriate for the risk of working with such materials.

An estimated 15,000 biomedical laboratories, in six categories of institutions: Academic, federal government, hospital, industry, private, and state and local government facilities, will be included in the final survey. We propose conducting pilot studies in 525 biomedical laboratories representing the above six categories. Specific survey strategies for each category will be refined through these pilot surveys. Three types of biomedical laboratories within each institutional category will be targeted by the pilot

survey: Those most likely to possess wild polio virus materials; those least likely to possess wild polio virus materials; and those that may possess wild polio virus materials.

The survey instruments will ask laboratories to indicate whether or not they possess wild polio virus infectious and/or potentially infectious materials. If such materials are present, respondents are asked to indicate the types of materials and estimated numbers retained. Survey instruments will be available on the NVPO web page, and institutions will be encouraged to submit completed survey forms electronically. The total burden for this data collection is 350 hours.

Respondents	Number of respondents	Responses/respondent	Average burden/response (in hours)
Labs most likely to possess .....	175	1	30/60
Labs least likely to possess .....	175	1	30/60
Labs that may possess .....	175	1	60/60

Dated: January 18, 2002.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Program Announcement 02027]

**Cooperative Agreement for the American Academy of Pediatrics; Notice of Availability of Funds**

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement program with the American Academy of Pediatrics (AAP). This program addresses the "Healthy People 2010" focus areas of Maternal, Infant and Child Health and Disability and Secondary Conditions.

The purpose of the program is to enhance public health practices related to birth defects and developmental disabilities by (1) promoting the professional development of pediatricians; (2) providing expert guidance on special topics on pediatric research and services; and (3) disseminating to practicing pediatricians information on birth

defects, developmental disabilities, and health promotion for children with disabilities.

Research involving human participants will not be supported under this cooperative agreement.

**B. Eligible Applicants**

Assistance will be provided only to the American Academy of Pediatrics (AAP). No other applications are solicited.

The AAP is regarded as the most influential and prestigious professional association for pediatricians in the United States, and is the only national professional association for general pediatricians in the United States. The recommendations produced by the AAP are considered among the most reliable and up-to-date information available to the pediatric community. Because of their strong reputation and large pediatric provider audience, the AAP can rapidly and efficiently disseminate information about birth defects and developmental disabilities issues to pediatricians across the country. The AAP's unparalleled ability to convey information to a large number of American pediatricians would make them an extremely useful asset in enhancing communications among practicing pediatricians. Because of their relationships with pediatricians and the mission of the organization, the AAP is a unique position to carry-out the work being proposed and is the only national organization that has the capacity and established provider network to conduct this project.

The AAP has a long-standing position as a trusted leader in the birth defects, developmental disabilities, and childhood disabilities fields.

AAP has a chapter in each state and territory that facilitates grass-roots interventions. In addition to its preeminence as a national organization of pediatricians, AAP is represented in all U.S. regions. This regional presence makes AAP the natural leader when local action is needed.

**Note:** Title 2 of the United States Code, section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

**C. Availability of Funds**

Approximately \$200,000 is available in FY 2002 to fund this award. It is expected that the award will begin on or about June 1, 2002, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

**D. Where to Obtain Additional Information**

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Click on "Funding" then "Grants and Cooperative Agreements."

To obtain business management technical assistance, contact: Sheryl

Heard, Grants Management Specialist, Acquisition and Assistance Branch B., Procurement and Grants Office, Centers for Disease Control and Prevention, Announcement 02027, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: 770-488-2723, E-mail: [slh3@cdc.gov](mailto:slh3@cdc.gov).

For program technical assistance, contact: Jack Stubbs, National Center on Birth Defects and Developmental Disabilities, 4770 Buford Highway, Mail Stop F-15, Atlanta, Georgia 30341, Telephone number: 770-488-7096, E-mail: [jbs2@cdc.gov](mailto:jbs2@cdc.gov).

Dated: January 22, 2002.

**Robert L. Williams,**

Chief, Acquisition and Assistance Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0590]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Salmonella Discovery System Pilot Study

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to construct and utilize a database from which FDA and pharmaceutical companies can share information based on their proprietary toxicology study data to predict the mutagenic response, mutagenic potency, and mechanism of mutagenesis of test chemicals in *Salmonella typhimurium*.

**DATES:** Submit written or electronic comments on the collection of information by March 29, 2002.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of

information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Karen Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions 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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Informatics and Computational Safety Analysis Staff intends to conduct a *Salmonella* Discovery System Pilot Study (the pilot study). The primary goal of the pilot study is to construct and execute a mutually beneficial process by which FDA and pharmaceutical companies can share information based on their proprietary toxicology study data and thereby expand their own knowledge databases. This process will be designed and

conducted using procedures that do not compromise the identity and chemical structures of the individual collaborator's proprietary chemicals.

The three major objectives of the pilot study are to:

- Build a joint and comprehensive FDA/pharmaceutical industry database for compounds tested in the *Salmonella t.* reverse mutagenicity assay;
- Use these data to construct a new enhanced *Salmonella t.* mutagenicity assay database module for the *Mu1tiCASE* quantitative structure activity relationship software program; and
- Employ the recently developed *Mu1tiCASE* expert system (*MCASE-ES*) to predict the mutagenic response, mutagenic potency, and mechanism of mutagenesis of test chemicals in *Salmonella t.*

The pilot study will be a joint venture designed to maximize the benefits and minimize the risks to all collaborators. FDA intends to send letters to companies that have purchased either *MultiCASE* or *CASETOXII* software programs to invite them to become a collaborator in the project.

FDA intends to request that each collaborator submit the following data electronically: (1) Test compound chemical structures; and (2) assay data, identifying the type of *Salmonella* mutagenicity assay used in the studies, the source and concentration of any exogenous activation system used, and the average number of revertants/plate for the negative control, positive control, and each of the test compound treatment groups. Although there is no minimum requirement for the number of test compounds to be submitted to FDA, the agency would expect to receive at least 200 compounds from each collaborator. Each company will be able to identify its own compounds in the resulting discovery system, and the more data submitted, the greater the coverage will be for each company's molecular universe.

FDA intends to act as the broker for the pilot study and will be responsible for the confidentiality and integrity of each collaborator's proprietary data. The number of compounds in the database module will depend upon the number of collaborators and the size of the data sets they contribute to the pilot study. After the enhanced *Salmonella* discovery system has been constructed and tested, FDA intends to custom prepare individual discovery systems for each collaborator.

The anticipated benefits to collaborators include:

- Receipt of a new expanded