

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day-02-74]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. National Center for Environmental Health (NCEH) is requesting an emergency clearance from the Office of Management and Budget (OMB) to collect data under the Paperwork Reduction Act. Send comments to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 14 days of this notice. We are requesting that OMB respond to CDC within 21 days after receipt of the package.

**Proposed Project**

Implementation of the National Cooperative Inner-City Asthma Intervention in Inner-City Poor Children treated through Managed Care Setting—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

The Inner-City Asthma Intervention (ICAI) program has implemented the National Cooperative Inner-City Asthma Study (NCICAS), a multi-faceted, multi-modal intervention designed to address a wide range of problems of the child with asthma and his or her family. NCICAS demonstrated that an individually tailored intervention

carried out by masters-level social workers trained in asthma management can reduce asthma symptoms among children in the inner city. The ICAI has been implemented in 23 urban areas to provide asthma education to poor, inner-city children aged 6-12 years with moderate to severe asthma and their families. This asthma intervention program is currently in year 2 of a 4 year contract period. An asthma counselor (master-level social worker) is employed at each site to tailor the one year asthma intervention to the needs of the individual child and the child's family. Each site enrolls 80 children in the intervention yearly through physician referral. The asthma counselor documents process variables including number of children enrolled in the intervention, retention rate, number of children and families completing key intervention components, and a narrative summary of lessons learned in conducting the intervention. This information is submitted quarterly to the contractor.

At the end of the four year project, this information will be summarized to determine the clinics' success in implementing the intervention protocol. There is no cost to the respondents other than their time. Time burden for response to the report may vary, but the average time to respond is 1 hour.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hours)	Total burden (in hours)
Asthma Counselor .....	23	4	1	92
Total .....				92

Dated: August 27, 2002.

**Nancy Cheal,**

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

[FR Doc. 02-22432 Filed 9-3-02; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[Program Announcement 02031]**

**Improving Effectiveness of the Tuberculosis Prevention and Control Program in Latvia; Notice of Award of Funds**

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a sole source cooperative agreement for the National Tuberculosis Control Program (NTP), Ministry of Health of the Government of Latvia.

The purpose of this program is to provide education and technical assistance to improve the quality,

efficiency, and effectiveness of programs for the prevention and control of tuberculosis (TB) in Latvia.

**B. Eligible Applicants**

Assistance will be provided only to the National Tuberculosis Control Program (NTP), Ministry of Health of the Government of Latvia. The NTP, Ministry of Health of the Government of Latvia is the most appropriate and qualified agency to conduct the activities under this cooperative agreement for the following reasons:

1. The NTP is uniquely positioned, in terms of legal authority, ability, track record, and credibility in Latvia to develop and implement TB control activities in both public sites throughout the country.

2. The NTP is currently involved in TB treatment services in Latvia, enabling it to immediately become

engaged in the activities listed in this announcement.

3. The purpose of the announcement is to utilize and build upon existing framework of TB control activities that the NTP has developed or initiated.

4. The NTP has been mandated by the Ministry of Health in Latvia to coordinate and implement TB treatment and control activities including Multi Drug Resistant TB (MDR-TB) within the country.

### C. Funds

Approximately \$105,000 is being awarded in FY 2002. The award will be made by September 1, 2002, for a 12-month budget period within a project period of up to five years.

### D. Where to Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Angelia D. Hill, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office,

Centers for Disease Control and Prevention, 2920 Brandywine Road, MS E-09, Atlanta, GA 30341-4146, Telephone: (770) 488-2785, FAX: (770) 488-2688, E-mail: [aph8@cdc.gov](mailto:aph8@cdc.gov).

Program Guidance may be obtained from: Michael Qualls, Deputy Associate Director, International Activities, Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road Mailstop E-10, Atlanta, GA 30333, Telephone 404-639-8488, e-mail address: [muq1@cdc.gov](mailto:muq1@cdc.gov).

Dated: August 27, 2002.

**Sandra R. Manning, CGFM,**

*Director, Procurement and Grants Office, Centers for Disease Control & Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Science and Regulation of Biological Products: From a Rich History to a Challenging Future; Public Symposium; Amendment

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

**ACTION:** Notice of public symposium; amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of public symposium entitled "Science and Regulation of Biological Products: From a Rich History to a Challenging Future." The public symposium was announced in the **Federal Register** of July 17, 2002 (67 FR 46993). The purpose of the symposium is to commemorate the 100th anniversary of the enactment of the Biologics Control Act, the first Federal law regulating biological products. The amendment is being made to reflect a change in the building location. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Gail Sherman, Center for Biologics Evaluation and Research (HFM-42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-2000, or e-mail: [Sherman@cber.fda.gov](mailto:Sherman@cber.fda.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 17, 2002, FDA announced that a public symposium entitled "Science and Regulation of Biological Products: From a Rich History to a Challenging Future" would be held on September 23 and 24, 2002, at the National Institutes of Health (NIH), Natcher Conference Center, Bldg. 45, 45 Center Dr., Bethesda, MD. On page 46993, in the first column, the *Location* section of this public symposium is amended to read as follows:

*Location:* The public symposium will be held at the National Institutes of Health (NIH), Warren Grant Magnuson Clinical Center, Bldg. 10, 10 Center Dr., Bethesda, MD 20892.

Dated: August 27, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02D-0368]

#### International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Draft Guidance for Industry on "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90-Day) Toxicity Testing" (VICH GL31); Request for Comments; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (t147) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90-Day) Toxicity Testing" (VICH GL31). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The objective of this draft guidance is to establish the minimum recommendations for an internationally harmonized 90-day repeat-dose testing strategy for identifying target organ toxicity and the no-observed adverse effect level (NOAEL) for toxicity of veterinary drug residues in human food based upon repeated dose 90-day toxicity studies for identifying target organ toxicity.

**DATES:** Submit written or electronic comments on the draft guidance by October 4, 2002 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: [lmulliga@cvm.fda.gov](mailto:lmulliga@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the