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#### SUPPLEMENTARY INFORMATION:

##### Background

In 2003, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) and U.S. Environmental Protection Agency (EPA) recommended that ICCVAM review the validation status of screening test methods that could be used to identify severe and irreversible ocular effects. ICCVAM unanimously agreed that the four *in vitro* test methods (IRE, ICE, BCOP, and HET-CAM) nominated by EPA should have high priority for evaluation. On March 24, 2004, NICEATM published a **Federal Register** notice (Vol. 69, No. 57, pp. 13859-13861) requesting all available data on these four *in vitro* ocular irritancy test methods and corresponding data from *in vivo* rabbit eye test methods, as well as any human exposure data (obtained either from ethical human studies or by accidental exposure). NICEATM subsequently compiled data and information on each test method and released four draft BRDs for public comment on November 3, 2004 (**Federal Register**, Vol. 69, No. 212, pp. 64081-64082).

On January 11-12, 2005, NICEATM, on behalf of ICCVAM, convened an expert panel meeting to independently assess the validation status of these four test methods. The panel's report was released in March 2005 (**Federal Register**, Vol. 70, No. 53, pp. 13513). Public comments at this meeting indicated that additional data on these *in vitro* test methods could be made available; therefore, the panel recommended that NICEATM obtain the additional data and reanalyze the accuracy and reliability of each test method. On February 28, 2005, NICEATM again solicited *in vitro* data on these four test methods and corresponding *in vivo* data (**Federal Register**, Vol. 70, No. 38, pp. 9661-9662). The revised analyses were published on July 26, 2005, as an addendum to the draft BRDs (**Federal Register**, Vol. 70, No. 142, pp. 43149).

NICEATM, on behalf of ICCVAM, reconvened the panel on September 19, 2005, to discuss the addendum to the draft BRDs (**Federal Register**, Vol. 70, No. 174, pp. 53676-53677). An addendum to the panel report was published in November 2005 (**Federal**

**Register**, Vol. 70, No. 211, pp. 66451). At its December 2005 meeting, the SACATM discussed and provided comments on the panel report and addendum (**Federal Register**, Vol. 70, No. 216, pp. 68069-68070) (minutes from that meeting are available at <http://ntp.niehs.nih.gov/go/8202>).

ICCVAM considered the expert panel report and its addendum, public comments, SACATM comments, and the draft BRDs and their addendums in finalizing its recommendations on the validation status of these four test methods. The ICCVAM Test Method Evaluation Report includes the ICCVAM recommendations on the use of each test method, as well as recommended test method protocols, recommendations for further optimization and validation studies, recommended reference substances for future validation studies, the panel report and its addendum, and **Federal Register** notices. The four final BRDs, which provide the supporting documentation for this report, are available as separate documents. The ICCVAM Test Method Evaluation Report and the supporting final BRDs were forwarded to U.S. Federal agencies for their consideration for regulatory acceptance as required by the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3). Agencies' responses to the test method recommendations will be posted on the ICCVAM/NICEATM Web site as they are received.

##### Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established January 9, 2002, and is composed of scientists from

the public and private sectors (**Federal Register**, Vol. 67, No. 49, page 11358). SACATM provides advice to the Director of the NIEHS, to ICCVAM, and to NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/> see "Advisory Board & Committees" (or directly at <http://ntp.niehs.nih.gov/go/167>).

Dated: November 13, 2007.

**Samuel H. Wilson,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-08-08AB]

#### 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 404-639-5960 and send comments to Maryam Daneshvar, Acting CDC Reports Clearance Officer, 1600 Clifton Road, MS-D 74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

*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. Written comments should be received within 60 days of this notice.

**Proposed Project**

All Age Influenza Hospitalization Surveillance (Flu Hosp)—New—National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

CDC is requesting OMB approval for a data collection system that will assist public health officials to better monitor and assess severe forms of influenza disease resulting in hospitalization. Approval is sought for an Adult Case Report Form and a Pediatric Case Report Form. The Adult Case Report Form will be used to collect information on patients over the age of 18 years old, and the Pediatric Case Report form will be used for patients under 18 years and younger. The primary difference between the two forms is that the Adult Case Report form includes collection of information related to Statin use, and the Pediatric Case Report form does not.

Adult surveillance will consist of two phases, a prospective data collection, and a retrospective discharge audit. Therefore, approval is also sought for

forms that will assess the completeness of the surveillance system's cases. These forms make up an Adult discharge audit, which will reveal any limitations in the prospective case identification that will have occurred prior to the discharge audit.

Flu Hosp uses standardized data collection instruments that collect demographic and clinical information from laboratory-confirmed influenza hospitalized adults and children who reside in a geographic- and population-defined area of the United States. The data collection network is an established CDC-state-academic institution collaborative network, the Emerging Infections Program (EIP) which includes the states of California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.

From October 1 of this year through April 30 of the following year (the current flu season), Flu Hosp collects data and transmits it to CDC. Case reports are submitted as soon as possible after the investigation of a case. Prompt notification to CDC allows for identification of epidemics and

outbreaks so that immediate prevention measures can be taken. Most of the data collection instrument can be completed from review of the hospital medical records. If none of these resources are available, the patient or their proxy may be interviewed.

CDC and its participating partners will also perform a discharge audit to assess the completeness of the case surveillance data by conducting an evaluation of the hospitalized influenza cases found by Flu Hosp versus an independent, administrative hospital dataset. Each of the ten participating sites will complete standardized forms that describe the evaluation process and the number of cases missed by Flu Hosp, in aggregate. Although 10 states participate in Flu Hosp, because New York includes two functionally and geographically different catchment areas, those two areas will submit individual discharge audit data, to make a total of 11 respondents.

The respondents for the data collections are the Flu Hosp participating sites. There are no costs to respondents other than their time for participating.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pediatric Influenza Hospitalization Surveillance Project Case Report Form.	Health Department ....	10	75	15/60	188
Adult Influenza Hospitalization Surveillance Project Case Report Form.	Health Department ....	10	120	15/60	300
Adult Discharge Audit Case Report Form .....	Health Department ....	11	3	15/60	8
Adult Discharge Audit Form A: Description of Matching Method.	Health Department ....	11	1	15/60	3
Adult Discharge Audit Form B: Sampling Strategy	Health Department ....	11	1	15/60	3
Adult Discharge Audit Form C: Summary .....	Health Department ....	11	1	15/60	3
Adult Discharge Audit Form D: Future .....	Health Department ....	11	1	15/60	3
Total .....	.....	.....	.....	.....	508

Dated: November 19, 2007.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention**

**[60Day-08-0692]**

**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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

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)