Dated: February 13, 2009.

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–09–09AR]

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 or send comments to Maryam Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *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

STD Surveillance Network (SSuN)—New—Division of STD Prevention (DSTDP); National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP); Centers for Disease Control and Prevention (CDC).

Backgroundand Brief Description

The STD Surveillance Network (SSuN) is a group of STD clinics and health departments designed to perform active surveillance for STDs, such as, chancroid, chlamydia, gonorrhea, syphilis, hepatitis B, HIV, trichomoniasis, genital warts, human Papillomavirus, and *Mycoplasma genitalium* at twelve health departments and STD clinics at: Alabama State Health Department, Baltimore City Health Department, Chicago City Health Department, Colorado State Health Department, Connecticut State Health Department, Los Angeles City Health Department, Louisiana State Health Department, New York City Health Department, Philadelphia City Health Department, San Francisco City Health Department, Virginia State Health Department, and Washington State Health Department.

These twelve active sentinel surveillance sites will provide detailed information on demographic characteristics, behavioral risk factors, and clinical history of ill persons in order to identify factors that sustain the epidemic. For example, history of previous STD, number and sex of sex partners, and participation in anonymous or commercial sex alter a person's risk for acquiring disease.

The objectives of the SSuN project are: (1) To establish an integrated network of sentinel STD clinics and health departments to inform and guide national programs and policies for STD control in the U.S.; (2) to improve the capacity of national, state, and local STD programs to detect, monitor, and respond to established and emerging trends in STDs, HIV, and viral hepatitis; and (3) to identify and evaluate the effectiveness of public health interventions to reduce STD morbidity.

Information for the SSuN will be obtained from two different areas; twelve sentinel STD clinics and twelve health departments who will conduct sentinel surveillance among individuals who are diagnosed with STDs in the general population.

Health Departments and the sentinel STD clinics are funded by CDC through a cooperative agreement for participation in the SSuN active surveillance. Clinical information of the patients with a STD is routinely entered into the STD clinic databases in an electronic form. In addition to the clinical data, STD clinic counselors will include a patient interview on sexual behaviors and practices, and clinical history which will also reside in the clinic databases. Data elements of interest to the SSuN will be extracted from the clinic databases on a quarterly basis and transmitted to CDC through a secured channel. Each STD clinic will spend 2 hours to transmit the data to CDC each quarter. At CDC, data will be aggregated with data from all participating sites in a common language and formatted for analysis.

The twelve Health departments serving as the SSuN sentinel surveillance sites will interview 67 persons from the community at large each quarter. Each interview is expected to take 7 minutes per person. The survey results will also be entered into the existing information systems at each health department and sent to CDC through a secure data network on a quarterly basis.

There is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondent	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
STD Surveillance Clinics	12	4	2	96
STD Patients	3216	1	7/60	375
Total				471

Dated: February 17, 2009.

Maryam I. Daneshvar,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0044]

Draft Guidance for Industry on Influenza: Developing Drugs for Treatment and/or Prophylaxis; 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 entitled ''Influenza: Developing Drugs for Treatment and/or Prophylaxis.'' Recent concerns about the possibility of pandemic spread of novel influenza strains have increased interest in influenza drug development for both seasonal and pandemic settings. The purpose of this guidance is to assist sponsors in all phases of influenza drug development and to address questions FDA often receives regarding the potential for emergency use of influenza drugs for the treatment and/or prophylaxis of influenza.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 21, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Debra Birnkrant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6332, Silver Spring, MD 20993–0002, 301–796–0770.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Influenza: Developing Drugs for Treatment and/or Prophylaxis.'' Because of the public health implications of both seasonal and pandemic influenza, the variable nature of the disease, and the limited therapeutic options and challenges in studying new options, FDA is developing guidance to assist sponsors in all phases of influenza drug development. This draft guidance addresses preclinical development, early phases of clinical development, phase 3 protocol designs and endpoints for the treatment of both uncomplicated and serious influenza, and protocol designs for the prophylaxis of symptomatic influenza. This guidance also addresses the role of animal data in an influenza drug development program and considerations relating to the potential for emergency use of influenza drugs including advance development of protocols for further exploration and verification of drug effects.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment and/or prophylaxis of influenza. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB Control Numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either*http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: February 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3554 Filed 2–19–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; A Process Evaluation of the NIH Director's New Innovator Award (NIA) Program

SUMMARY: 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 Office of the Director, the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: A Process Evaluation of the NIH Director's New Innovator Award (NIA) Program. *Type of Information Collection Request:* New collection. *Need and Use of Information Collection:* This study will assess the NIA Program operations and the outputs of the identification, evaluation and selection process. The primary objectives of the study are to: (1) Assess the NIA award selection process; (2) determine if the program was implemented as planned; and (3) determine if the process was conducted in accordance with the overall mission of the NIA program. The findings will provide valuable information concerning: (1) The characteristics of applicants and reviewers; (2) the criteria used to evaluate and select awardees; and (3) aspects of the process that could be revised or improved.

Frequency of Response: Once. *Affected Public:* none. *Type of*