Dated: February 17, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–3647 Filed 2–19–09; 8:45 am]

BILLING CODE 4163–18–P

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Draft Guidance for Industry on Influenza: Developing Drugs for Treatment and/or Prophylaxis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Influenza: Developing Drugs for Treatment and/or Prophylaxis.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 21, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Influenza: Developing Drugs for Treatment and/or Prophylaxis.''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]

BILLING CODE 4160–01–S

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*

Respondents: Applicants, Reviewers. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 662; *Estimated Number of Responses per Respondent:* 1: *Average Burden Hours Per Response:* .28 (15 minutes for applicants and 30 minutes for Extramural Reviewers), and *Estimated Total Annual Burden Hours Requested:* 188.5 and the annualized cost to respondents is estimated at $12,199.72. Table l and Table 2 respectively present data concerning the burden hours and cost burdens for this data collection.

TABLE 1—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time for response (hr)	Total hour burden*
Applicants	570	1	.25	142.5
Extramural Reviewers	92	1	.50	46
Total	662	1	.28	188.5

*Total Burden = N Respondents*Response Frequency*(minutes to complete/60).*

TABLE 2—ANNUALIZED COST TO RESPONDENTS

Type of respondents	Number of respondents	Response frequency	Approx. hourly wage rate	Total respondent cost**
Applicants	570	1	$64.72	$9,226.60
Extramural Reviewers	92	1	64.72	2977.12
Total	662	1	64.72	12,199.72

**Total Respondent Cost = Total Hour Burden * Hourly Wage Rate.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact G. Stephane Philogene, Ph.D., Assistant Director for Policy and Planning, Office of Behavioral and Social Sciences Research, National Institutes of Health, 31 Center Drive. Building 31, Room B2–B37, Bethesda, MD 20892, or call non-toll-free number (301) 402–3902 or e-mail your request, including your address to: *philoges@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 10, 2009.

G. Stephane Philogene,

Assistant Director for Policy and Planning, Office of Behavioral and Social Sciences Research, National Institutes of Health.

[FR Doc. E9–3584 Filed 2–19–09; 8:45 am]

BILLING CODE 4140–10–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group, Minority Programs Review Subcommittee B.

Date: March 13, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rebecca H. Johnson, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 12, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–3581 Filed 2–19–09; 8:45 am]

BILLING CODE 4140–01–P