

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Draft Guidance for Industry on Influenza: Developing Drugs for Treatment and/or Prophylaxis; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Influenza: Developing Drugs for Treatment and/or Prophylaxis."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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 21, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled "Influenza: Developing Drugs for Treatment and/or Prophylaxis."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

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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*