

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0439]

DDM

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Publication Date 11-23-07  
Certifier A. Corbin

**Draft Guidance for Industry on Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention." In this draft guidance, FDA provides recommendations on the development of drugs to be used to treat or prevent smallpox (variola) infection. This guidance is intended to help sponsors plan and design appropriate studies during the development of these drugs.

**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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 Submit written comments on the draft guidance to the Division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.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Debra B. Birnkrant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6332, Silver Spring, MD 20993-0002, 301-796-1500.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention.” This guidance provides recommendations on the development of drugs to be used to treat or prevent smallpox (variola) infection. The study of smallpox drug development poses special challenges in drug development because of the unique attributes of the pathogen. Therefore, this guidance focuses on the importance of pre-investigational new drug application interactions between sponsors and FDA, appropriate approaches to nonclinical studies in early drug development, generation and use of supporting data from related poxviruses, design and characterization of animal models, approaches to clinical trials including safety studies, advance preparation of protocols for potential use in emergency settings, and use of combinations of animal and human data.

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 to treat or prevent

smallpox (variola) infection. 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. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 312 have been approved under OMB Control No. 0910–0014.

## **III. Comments**

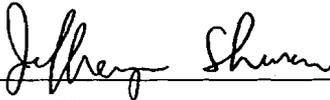
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

**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.fda.gov/ohrms/dockets/default.htm>.

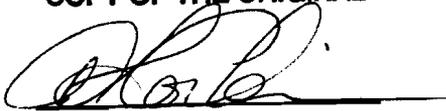
Dated: NOV 15 2007  
November 15, 2007.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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