

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM  
Display Date 3-8-04  
Publication Date 3-9-04  
Certifier R. LEDESMA

[Docket No. 2003D-0553]

**Draft Guidance for Industry on Vaccinia Virus—Developing Drugs to Mitigate the Complications Associated With Vaccinia Virus Used for Smallpox Vaccination; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Vaccinia Virus—Developing Drugs to Mitigate the Complications from Smallpox Vaccination.” In this draft guidance, FDA provides recommendations on the development of drugs to be used to treat complications that may occur from smallpox vaccination with vaccinia virus. This draft guidance is intended to help research sponsors plan and design appropriate nonclinical and clinical studies during the development of these drugs.

**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division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 See **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Lewis Schrager, Center for Drug Evaluation and Research (HFD-970), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7265, or Debra Birnkrant, CDER (HFD-530), 301-827-2330;

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210; or

Steve Gutman, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-3084.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

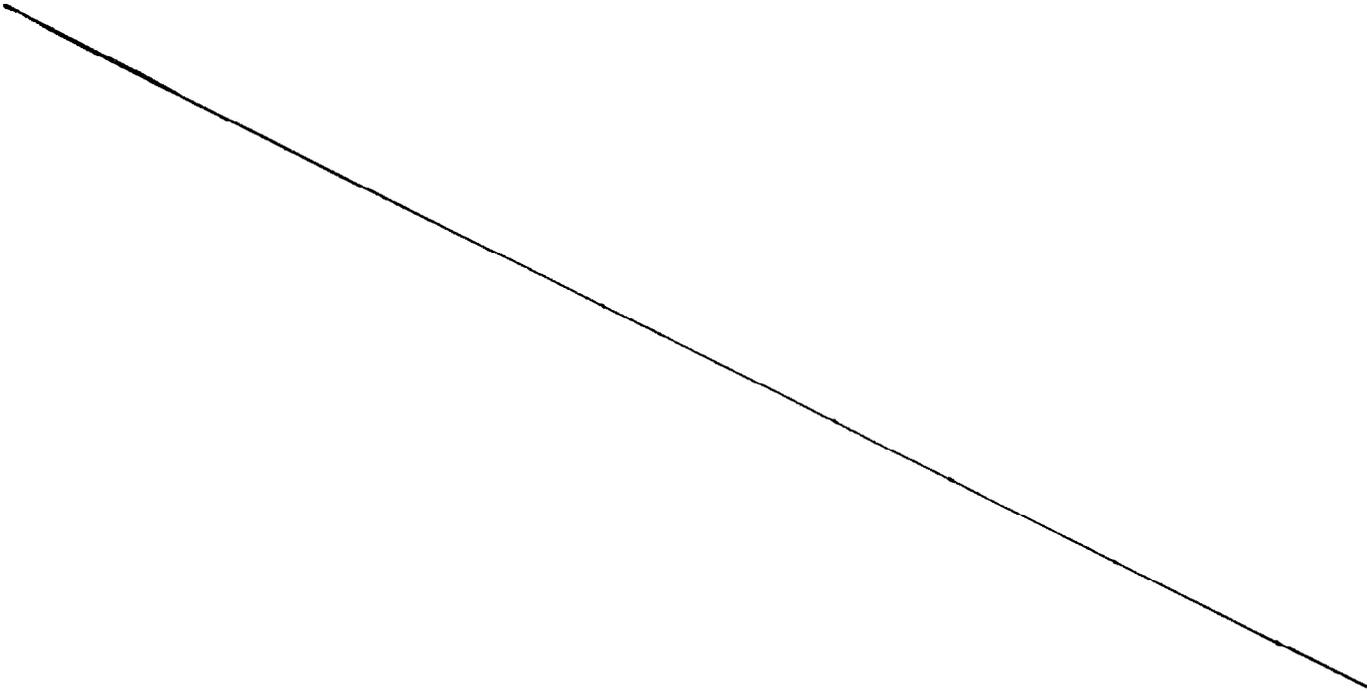
FDA is announcing the availability of a draft guidance for industry entitled “Vaccinia Virus—Developing Drugs to Mitigate the Complications from Smallpox Vaccination.” This draft guidance provides recommendations on the development of drugs to be used to treat complications that may occur from smallpox vaccination with vaccinia virus. The study of vaccinia complications poses challenges in drug development, such as sparse human data. Therefore, this draft guidance focuses on the design and characterization of animal models and of clinical trials and on the use of combinations of animal and human data. In addition, this draft guidance addresses data collection encompassing both preterrorism event controlled vaccination and

postterrorism event emergent vaccination. It also addresses the collection of long-term and special population safety data.

This level 1 draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking on developing drugs to mitigate the complications associated with vaccinia virus used for smallpox vaccination. 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 or regulations.

## **II. Comments**

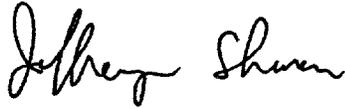
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Persons with access to the Internet may obtain this document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 3/2/04  
March 2, 2004.



---

Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**

