

4. Organizes, plans, and directs the Center for research support in the areas of Tobacco.

Directs the development methods used to extrapolate test results from animals to humans.

5. Coordinates research in Center program areas with leading scientists in other segments of FDA and the scientific community at large and promotes and coordinates the Center's technology transfer under the provisions of the Federal Technology Transfer Act.

6. Coordinates with other Center and agency components and top level officials of other agencies to provide input for long-term research planning in responsible program areas.

7. Insures that programs implemented are responsive to the Center's portion of the agency's integrated research plan.

8. Provides scientific oversight of Center research contracts and agreements.

9. Advises and assists the Center Director, Deputy Director, and other key officials on scientific issues that have an impact on policy, direction, and long-range goals.

10. Coordinates and provides guidance on special and overall science policy in program areas that cross major agency component lines and scientific aspects that are critical or controversial, including agency risk assessment policies.

11. Represents the Center with other government agencies, state and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on tobacco science policy and tobacco science issues.

12. Serves as the focal point for overall management of Center activities related to science priorities, resources, and leveraging efforts, as well as peer review of scientists and scientific programs.

13. Advises the Commissioner, Deputy Commissioner, and other key officials on scientific facilities and participates with other agency components in planning such facilities.

14. Administers the Tobacco Advisory Committee that advises the Center Director, Deputy Director, and other key officials regarding the quality and direction of tobacco science and scientific issues.

II. Delegation of Authority. Pending further delegation, directives or orders by the Commissioner of the Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further

redelegations, provided they are consistent with this reorganization.

Dated: August 7, 2009.

Kathleen Sebelius,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Development of Antiviral Products for Treatment of Smallpox and Related Poxvirus Infections; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding scientific issues in clinical development of antiviral drug products for treatment of smallpox and related poxvirus infections. This public workshop is intended to provide information for and gain perspective from health care providers, academia, and industry on various aspects of antiviral product development for smallpox and related poxvirus infections, including the status of clinical understanding of smallpox from pre-eradication experience, current epidemiology of naturally occurring poxvirus infections, potential effect of antiviral treatment for smallpox and related poxvirus infections, and issues pertaining to animal models for smallpox and related poxvirus infections. The input from this public workshop will help in developing topics for further discussion.

Dates and Times: The public workshop will be held on September 1, 2009, from 8:30 a.m. to 5:30 p.m. and on September 2, 2009, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Crowne Plaza Silver Spring, 8777 Georgia Ave., Silver Spring, MD 20910.

Contact Person: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to SmallpoxWkshp@fda.hhs.gov by August

24, 2009. Persons without access to the Internet can call 301-796-1300 to register. Registration is free for the public workshop, but interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding antiviral drug development for smallpox and related poxvirus infections. This public workshop will focus on scientific considerations in the clinical development of products for treatment of smallpox and related poxvirus infections. This public workshop is intended to provide information regarding historical perspectives on smallpox and current perspectives on related poxvirus infections in humans. The workshop will explore approaches to assessing the potential effect of antiviral treatment for smallpox and related poxvirus infections. Issues pertaining to animal models for smallpox and related poxvirus infection and their relationship to disease in humans will be discussed at the workshop. In addition, the workshop will include perspectives of public health organizations on possible uses of an antiviral product for poxvirus infections.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm169065.htm> approximately 45 days after the workshop.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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