

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM

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[Docket No. FDA-2008-N-0038]

Animal Models for the Treatment of Acute Radiation Syndrome; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, and the National Institutes of Health, National Institute of Allergy and Infectious Diseases, are announcing a public workshop entitled "Animal Models for the Treatment of Acute Radiation Syndrome (ARS)." The purpose of the public workshop is to discuss issues that should be considered when developing animal models to assist in developing and demonstrating the efficacy of products intended for treatment of ARS.

Date and Time: The public workshop will be held on September 17, 2008, from 8:30 a.m. to 5:30 p.m., and on September 18, 2008, from 8:30 a.m. to 1 p.m.

Location: The public workshop will be held at the Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079; e-mail: CBERTraining@fda.hhs.gov (Subject line: Animal Models for ARS Workshop).

Registration: Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 25, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: There are no approved medical products with an indication for treatment of ARS. The public workshop will provide the opportunity to explore current research involving animal models for the development of treatments for ARS, and to determine what areas need further research. There will be feature presentations by experts from government, academia, and medicine. The first day of the workshop will include presentations on the effects of radiation and the management of patients with ARS, and a discussion of the application of the animal rule to therapies for ARS. Both days of the workshop will examine the challenges faced when using animal models to mimic radiation exposure scenarios and will include panel discussions that will focus on various animal models and their application to the different syndromes of ARS.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: 7/11/08

July 11, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins