influenza drug of the neuraminidase inhibitor class, was recommended for treatment of and/or for prophylaxis in pregnant women during the 2009 H1N1 influenza pandemic. In addition, two clinical studies conducted in pregnant women provide some pharmacokinetic data for oseltamivir.

This workshop is open to all interested parties. The target audience includes professionals in the scientific community interested in discussing the challenges of evaluating medical countermeasures for effective and safe use during pregnancy.

The workshop will include plenary and breakout sessions on the scientific challenges in the development of animal models of pregnancy that can be used to address the safety and efficacy of medical countermeasures. Broad topics to be covered in the plenary sessions include: (1) The physiology and pharmacology of pregnancy as it relates to model development; (2) the role of animal models in evaluating medical countermeasures, including influenza therapies, that may be used during pregnancy; and (3) experimental design considerations. Topics of the breakout sessions will include: (1) Animal model selection, (2) design of the pharmacokinetic studies, and (3) additional issues in experimental design.

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted, as it becomes available, on the registration Web site at http://fda.contractmeetings.com.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.


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