

Dated: January 30, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 25, 2002, from 8:30 a.m. to 5:30 p.m., and February 26, 2002, from 8 a.m. to 5 p.m.:

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Nancy Chamberlin, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or e-mail: CHAMBERLIN@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 25, 2002, the subcommittee will: (1) Identify and define technology and regulatory uncertainties/hurdles, possible solutions, and strategies for the successful implementation of process analytical technologies (PATs) in pharmaceutical development and manufacturing; (2) discuss general principles for regulatory application of PATs including principles of method validation, specifications, use and validation of chemometric tools, and feasibility of parametric release concept; and (3) discuss the need for a general

FDA guidance to facilitate the implementation of PATs.

On February 26, 2002, the subcommittee will discuss strategies to explore issues in the following four focus areas: (1) Product and process development, (2) process and analytical validation, (3) chemometrics, and (4) process analytical technologies, applications and benefits.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by February 15, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 25, 2002, and between approximately 1:30 p.m. and 2 p.m. on February 26, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 15, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nancy Chamberlin at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 31, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0027]

Swine Mycoplasma Pneumonia Technical Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop: Swine Mycoplasma Pneumonia Technical Workshop. The topic to be discussed is how to evaluate drug effectiveness against swine mycoplasma respiratory disease.

Date and Time: The public workshop will be held on March 6 and 7, 2002, 8:30 a.m. to 4:30 p.m. Submit written or electronic comments by May 6, 2002.

Addresses: The public workshop will be held at the DoubleTree Hotel Kansas City, 1301 Wyandotte St., Kansas City, MO 64105, 816-474-6664. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

For General Information Contact: Gillian A. Comyn, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7568, FAX 301-594-2298.

For Information About Registration Contact: Irma Carpenter, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7580, FAX 301-594-2298.

Registration: Registration is required. There is no registration fee for the meeting. Space is limited. Registration will be on a first come, first served basis. Information about the workshop is available on the Internet at the Center for Veterinary Medicine (CVM) Web site at <http://www.fda.gov/cvm>. Electronic registration for the workshop is available at <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>. Alternatively, please send registration information (including name, title, firm name, address, telephone, and fax number) to Irma Carpenter (address above). If you need special accommodations due to a disability, please contact the DoubleTree Hotel Kansas City at least 7 days in advance at 816-474-6664, and Irma Carpenter at 301-827-7580.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is seeking scientific input from a broad public forum to help the agency determine an acceptable method, in light of the current state of scientific knowledge, for evaluating drug effectiveness against swine mycoplasma respiratory disease. *Mycoplasma hyopneumoniae* is a major pathogen in "porcine respiratory disease complex" (PRDC). PRDC is a significant problem in the swine industry in the