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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0027]

Swine Mycoplasmal 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 Mycoplasmal Pneumonia Technical Workshop. The topic to be discussed is how to evaluate drug effectiveness against swine mycoplasmal 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://>

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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 mycoplasmal 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 United States and abroad. This workshop will provide a necessary forum for leveraging scientific resources, including top experts in swine mycoplasmal pneumonia. The workshop is part of CVM’s leveraging initiative aimed at increasing interaction with industry, academia, practitioners, and other government agencies.

II. Agenda

The preliminary agenda is as follows:

Session 1: The disease—history, clinical presentation, epidemiology, and economics;

Session 2: Cutting edge—new findings on the organism;

Session 3: Perspectives from industry, producers, veterinarians, and government regulators;

Session 4: Breakout exercise;

Panel discussion;

Adjourn.

Proposed core items for discussion include:

1. Define swine mycoplasmal pneumonia.

- *M. hyopneumoniae* as a pathogen in PRDC, enzootic pneumonia.
- The disease(s) in clinical and field settings.
- Epidemiology: Disease determinants, risk factors, and confounders.
- Methods for diagnosing pneumonia associated with *M. hyopneumoniae*.
- The disease contribution of *M. hyopneumoniae* in PRDC.

2. Methods of detection of *M. hyopneumoniae* in body tissues and fluids.

- Proper sampling for different methods.
- Comparison of detection methods for sensitivity, specificity, and positive and negative

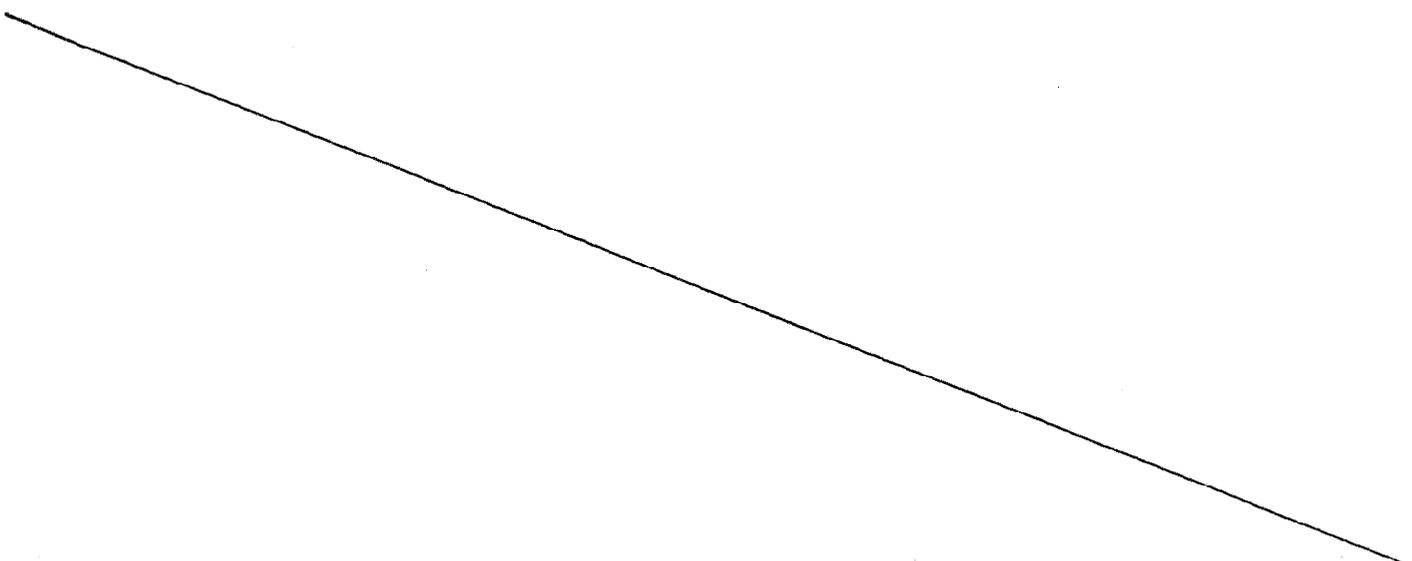
predictive test values.

3. What is the best study design for demonstrating effectiveness of treatments against pneumonia associated with *M. hyopneumoniae* infection?

• What is a “cure” in swine mycoplasmal pneumonia, and what are the best clinical and laboratory indicators?

- Study designs.
- Perspectives on designing studies to demonstrate effectiveness of therapeutic modalities

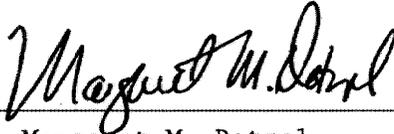
against pneumonia in swine associated with *M. hyopneumoniae* infection.

- Substantial evidence.
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III. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this workshop until May 6, 2002. Comments are to be identified with the docket number found in the brackets in the heading of this document.

Dated: 1-30-02
January 30, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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