Dated: January 30, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–2883 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S

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: CHAMBERLINN@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 maybe 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.

[FR Doc. 02–2882 Filed 2–5–02; 8:45 am]

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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://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.

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: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2752 Filed 2–6–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0032]

Guidance for Industry; Implementation of Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, Pub. L. No. 107–76, § 755 (2001) Regarding Common or Usual Names for Catfish; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry; Implementation of Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, Pub. L. No. 1076–76, § 755 (2001) regarding Common or Usual Names for Catfish.'' Section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002, provides that FDA may not spend any of its 2002 appropriation to allow admission of fish or fish products labeled in whole or in part with the term ''catfish'' unless the fish are from the *Ictaluridae* family. This guidance discusses how FDA plans to exercise enforcement discretion with regard to certain fish whose common or usual name contains the term ''catfish.''

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Seafood (HFS–400), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the guidance may be sent. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2303, FAX 301–436–2599.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of guidance for industry implementing section 755 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2002 (Public Law 107–76, § 755 (2001), which provides that FDA may not spend any of its 2002 appropriation to allow admission of fish or fish products labeled in whole or in part with the term ''catfish'' unless the fish are from the *Ictaluridae* family. This guidance discusses how FDA plans to exercise enforcement discretion with regard to certain fish whose common or usual name contains the term ''catfish''.

This guidance is a level 1 guidance issued consistent with FDA's regulation on good guidance practices (GGPs) (§ 10.115 (21 CFR 10.115)) relating to the development, issuance, and use of guidance documents. Consistent with GGPs, the agency is soliciting public comment, but is implementing the guidance document immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. FDA's 2002 appropriation law was enacted on November 28, 2001, and section 755 is now in effect and must be implemented immediately. There is a need for guidance to help effect such implementation. Thus, FDA is making the guidance effective immediately.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments on the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http:/