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]

BILLING CODE 4160–01–S

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:/

/www.cfsan.fda.gov/dms/guidance/html or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 18, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2753 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0005]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Draft Guidance for Industry on ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#143) entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30). This draft guidance has been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft guidance addresses the process for developing a controlled list of terms in order to assure that terms are used consistently in adverse event reports, and to allow comparison between products and across product classes. This draft guidance is limited to developing a controlled list of terms describing veterinary medicinal products (VMPs), animals, clinical signs, and associated body systems and organs for reporting an adverse event associated with the use of a VMP.

DATES: Submit written or electronic comments on the draft guidance by March 8, 2002, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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*. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6642, e-mail: *wkeller@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for VMPs. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Controlled List of Terms

The VICH Steering Committee held a meeting on June 28, 2001, and agreed that the draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms'' (VICH GL30) should be made available for public comment.

A controlled list of terminology is essential to ensure consistent evaluation of adverse event reports and electronic submission of these reports on a national and international basis. This draft guidance provides recommendations for adopting and managing a controlled list of terminology used to describe veterinary medicinal products, animals, clinical signs, and associated body systems and organs in adverse event reports. Components of the recommendations are directed at regulatory authorities and should be implemented by these agencies as well as by regulated industry.

The VICH closely followed the progress of its human counterpart, ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), in implementing a standardized controlled terminology and believes that with appropriate modification the same approach will be viable for the VICH. Thus, the approach outlined in the guidance document is based on identification of similar technical terminology needs and an approach for meeting those needs used by ICH to develop MedDRA (Medical Dictionary for Drug Regulatory Activities), the international terminology for reports to regulatory authorities describing human adverse events.

These recommendations include that government and industry partner together in development,