REGISTRATION: There is no registration fee, however, space is limited. Persons will be registered in the order in which calls are received. Please call Betty B. Palsgrove at 301–827–6618 to register. Registrations also may be transmitted by fax to 1–800–344–3332 or 301–443–2446. Please include the name and title of the person attending and the name of the organization.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, M.D., J.D., Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6630.

SUPPLEMENTARY INFORMATION:

The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1850 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Imaging Drugs Advisory Committee; 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Medical Imaging Drugs Advisory Committee.

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

Date and Time: The meeting will be held on February 9, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–80–741–8138 (301–443–0572 in the Washington, DC area), code 12540. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 20–887 AcuTect™, Diatide, Inc., a radiopharmaceutical agent for the detection and localization of acute venous thrombosis.

Procedure: On February 9, 1998, from 8 a.m. to 1 p.m. and from 2 p.m. to 5 p.m. the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 2, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 1998, 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.

Closed Committee Deliberations: On February 9, 1998, from 1 p.m. to 2 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information relating to NDA 20–887 AcuTect™ (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the February 9, 1998, Medical Imaging Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Imaging Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2022 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on Validation of Analytical Procedures: Definition and Terminology (#63), and Validation of Analytical Procedures: Methodolgy (#64); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of two draft guidance for industry (GFI) documents entitled ''Validation of Analytical Procedures: Definition and Terminology'' (number 63) and ''Validation of Analytical Procedures: Methodology'' (number 64). These related draft GFI documents have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from two guidelines, Q2A and Q2B, that were adopted by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The draft guidance is intended to provide guidance on characteristics that should be considered during the validation of analytical procedures included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments on these draft GFI documents by March 30, 1998.

ADDRESSES: Submit written comments on the two draft GFI documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Comments should be identified with the full title of the draft GFI document and the docket number found in the heading of this document.

Submit written requests for single copies of these draft GFI documents to the Communications and Education Team (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Copies of these draft guidance documents may be obtained on the Internet from the CVM Home Page (http://www.cvm.fda.gov).

FOR FURTHER INFORMATION CONTACT:

Regarding the GFI's: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678. E-mail: wmarnane@bangate.fda.gov.

Regarding VICH: Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798. E-mail: sthompso@bangate.fda.gov.

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

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the registration of human pharmaceutical products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary pharmaceutical products. The VICH is concerned with developing harmonized technical requirements for the registration of veterinary pharmaceutical products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Épizooties (OIE). During the initial phase of the VICH, an OIE representative chairs the VICH Steering Committee. The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the U.S. Food and Drug Administration; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, one representative from the industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. 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.

At a meeting held on August 20 and 21, 1997, the VICH Steering Committee agreed that the draft GFI documents entitled ''Validation of Analytical Procedures: Definition and Terminology'' and ''Validation of Analytical Procedures: Methodology'' should be made available for public comment. These draft GFI documents were prepared by the VICH Quality Working Group and are based on the ICH Guidelines (Q2A and Q2B) that have already been adopted by FDA for human pharmaceuticals. With one exception, the deletion of the text ''(e.g. metered dose inhalers)'' included in the ICH guideline Q2B, Section 3, the documents are identical.

The draft GFI document entitled, ''Validation of Analytical Procedures: Definition and Terminology,'' discusses the characteristics that should be considered during the validation of the analytical procedures included in an application for registration of veterinary medicinal products in the European Union, Japan, and the United States. This document pertaining to ''Definition and Terminology'' is not intended to cover testing requirements or procedures, rather it is intended to serve as a collection of terms and definitions. These common definitions such as ''analytical procedures,'' ''specificity,'' ''precision,'' ''accuracy,'' etc., are meant to bridge the differences that often exist among various compendia and requirements of the European Union, Japan, and the United States. The draft GFI document entitled, ''Validation of Analytical Procedures: Methodology,'' discusses common analytical procedures and provides guidance and recommendations on how to consider various validation characteristics for each analytical procedure. It also indicates the data that should be included in an application for registration. Comments about these draft GFI documents will be considered by the FDA and the VICH Quality Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidelines and publish them as future GFI documents.

If finalized, these documents will represent current FDA thinking on characteristics for consideration during the validation of the analytical procedures included as part of applications. The draft GFI documents will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

Interested persons may, on or before March 30, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and with the full title of the guidance document. The comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. After review of these comments, FDA will implement the guidance document with any appropriate changes. Thereafter, interested persons may submit written comment on the guidance document directly to the CVM Communications and Education Team (address above).

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1848 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

ACTION: Notice.

SUMMARY: The collection of information described below will be submitted to OMB for approval under the provisions