Dated: December 27, 2001.

Kathy Cahill,

Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–197 Filed 1–3–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices 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). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

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 January 17, 2002, from 9:30 a.m. to 5 p.m., and January 18, 2002, from 8:30 a.m. to 3:30 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 17, 2002, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) on an endocapsular tension ring for the stabilization of the lens capsular bag. On January 18, 2002, the committee will discuss, make recommendations, and vote on a PMA on an orthokeratology contact lens for corneal refractive therapy with overnight wear for the temporary reduction of myopia. Background information for each day's topic, including the agenda and questions for the committee, will be available to the public one business day before the meeting, on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the January 17 session will be posted on January 16, 2002; material for the January 18 session will be posted on January 17, 2002.

Procedure: 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 January 7, 2002. On January 17, 2002, formal oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m., and on January 18, 2002, between approximately 8:45 and 9:15 a.m. Near the end of the committee deliberations on each PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Those desiring to make formal oral presentations should notify the contact person before January 7, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the January 17 and 18, 2002, Ophthalmic Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs 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: December 28, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–152 Filed 1–3–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1631]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance for Industry on ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#116) entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing'' (VICH GL23). This final guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This final VICH guidance document recommends a basic battery of tests that can be used to evaluate the genotoxicity of veterinary drug residues in human food in the European Union, Japan, and the United States.

DATES: Submit written or electronic comments on this final guidance at any time.

ADDRESSES: Submit written requests for single copies of the final 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. Submit written comments on the final 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 final guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance.

FOR FURTHER INFORMATION CONTACT: Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: lmulliga@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 ICH 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 veterinary medicinal products. 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. Final Guidance on Genotoxicity Studies

In the **Federal Register** of December 18, 2000 (65 FR 79106), FDA published the notice of availability of the VICH draft guidance, giving interested persons until January 17, 2001, to submit comments. After consideration of comments received, the final draft guidance was changed in response to the comments and submitted to the VICH Steering Committee. At a meeting held on June 28, 2001, the VICH Steering Committee endorsed the final guidance for industry, VICH GL23. Following the endorsement of the final guidance document by the VICH Steering Committee, a change was made to the document in which the reference for each genotoxicity test in the basic battery of tests was moved and used as the heading for the paragraph describing that test. The change was of an editorial nature and did not change the scientific content or intent of the guidance document.

This guidance is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. This guidance was developed after consideration of the existing ICH guidances for pharmaceuticals for human use entitled ''Genotoxicity: A Standard Battery of Genotoxicity Testing of Pharmaceuticals'' and ''Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals.'' Account was also taken of the Organization for Economic Cooperation and Development methodological guidances and of the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the U.S.A., Australia, and New Zealand.

This level 1 final guidance document is developed under the VICH process and is consistent with FDA's good guidance practices regulation (21 CFR 10.115). This document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

(Information collection is covered under OMB control number 0910–0117.)

III. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this 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. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cvm.

Dated: December 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–193 Filed 1–3–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1630]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on ''Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing'' (VICH GL22); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#115) entitled ''Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing'' (VICH GL22). This final guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding