

Dated: December 27, 2001.

Kathy Cahill,

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

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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.

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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.