Nonprescription Drugs Advisory Committee to represent industry interests should send a letter stating that interest to the FDA employee designated in the notice within 30 days of the date of this notice. After 30 days, a letter will be sent to each organization that has expressed an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting a single nonvoting member to represent industry interests for that committee within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

Individuals and organizations may nominate individuals to serve as the nonvoting industry representative. To do so, a current curriculum vitae should be sent to the contact person. FDA will forward any nominations to the organizations expressing interest in participating in the selection process. The organizations are under no obligation to select any of these nominees but may do so if they wish.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 14, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–15666 Filed 6–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0219]

Serono, Inc.; Withdrawal of Approval of a New Drug Application; Breokinase®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing, without prejudice, approval of a new drug application (NDA) for Breokinase® (Urokinase for Injection) held by Serono, Inc., 100 Longwater Circle, Norwell, MA 02061. Serono, Inc., notified the agency in writing that it does not intend to introduce Breokinase® into the U.S. market or export Breokinase® from the United States, and voluntarily requested that the approval of the application be withdrawn and thereby waived its opportunity for a hearing.

DATES: Effective July 23, 2001.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In a letter to FDA dated October 10, 2000, Serono, Inc., voluntarily requested the withdrawal of NDA 17–873 for Breokinase® (Urokinase for Injection). Serono, Inc., neither intends to market the product in the United States nor export it from the United States. The firm voluntarily requested that FDA withdraw NDA 17–873, and therefore has waived its opportunity for a hearing. In a December 13, 2000, letter to the firm, FDA acknowledged receipt of the request and stated it would proceed (to publish a **Federal Register** notice) withdrawing the NDA.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.82), approval of the application listed in this document, and all amendments and supplements thereto, is hereby withdrawn, as of July 23, 2001.

Dated: May 18, 2001.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 01–15720 Filed 6–21–01; 8:45 am]

BILLING CODE 4160–01–S

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). At least one portion of the meeting will be closed 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 July 20, 2001, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact: 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: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for soft contact lenses for the optical correction of refractive ametropia in phakic or aphakic persons with nondiseased eyes with up to approximately 1.50 diopters of astigmatism. The lenses may be prescribed for extended wear for up to 30 nights of continuous wear between removals for cleaning and disinfection or for disposal of the lens, as recommended by the eye care professional. Background information, including the agenda and questions for the committee, will be made available to the public on July 19, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: On July 20, 2001, from 9:30 a.m. to 3:30 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 July 13, 2001. Formal oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Time allotted for each presentation may be limited. Near the end of the committee deliberations on the 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 July 13, 2001, 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 July 20, 2001, from 3:30 p.m. to 5 p.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4))