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market or export Breokinase® from the United States, and voluntarily requested that the approval of the application be withdrawn and thereby waived its opportunity for a hearing.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))

regarding pending issues and applications.

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

Dated: June 14, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–15667 Filed 6–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel NCCAM H–12 SEP.

Date: June 21, 2001.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Cecelia Maryland, Grants Technical Assistant, National Center for Complementary and Alternative Medicine, National Institutes of Health, Building 31, Room 5B50, Bethesda, MD 20892, (301) 480–2419.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: June 18, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–15760 Filed 6–21–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Mentored Patient-Oriented Research Career Development Award (K23).

Date: June 25, 2001.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: 6701 Rockledge, Room 5106, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Diane M. Reid, MD, Review Branch, Room 7182, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892, (301) 435–0277.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 18, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–15761 Filed 6–21–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Population Research Subcommittee.

Date: June 28–29, 2001.

Time: 7:30 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Hyatt Regency Hotel, 100 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Jon M. Ranhand, Ph.D, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Blvd., Rm. 5E01, MSC 7510, Bethesda, MD 20892, (301) 435–6884.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: June 18, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–15753 Filed 6–21–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant