

sought with experience and success in activities specified in the summary paragraph above, through which the Agency carries out its work.

**DATES:** Nominations should be received on or before July 13, 2001.

**ADDRESSES:** Nominations should be sent to Ms. Anne Lebbon, AHRQ, 2101 East Jefferson Street, Suite 600, Rockville, Maryland 20852. Nominations also may be faxed to (301) 443-0251.

**FOR FURTHER INFORMATION CONTACT:** Ms. Anne Lebbon, AHRQ, at (301) 594-7216.

**SUPPLEMENTARY INFORMATION:** 42 U.S.C. 299c, section 921 of the PHS Act, provides that the National Advisory Council for Health and Research and Quality shall consist of 21 appropriately qualified representatives of the public appointed by the Secretary of Health and Human Services and eight ex officio representatives from Federal agencies conducting or supporting health care research. The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ's Director on the direction and programs for AHRQ.

Seven individuals will presently be selected by the Secretary to serve on the Council beginning with the meeting in the fall of 2001. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Nominations shall include a copy of the nominee's resume or curriculum vitae, and state that the nominee is willing to serve as a member of the Council. Potential candidates will be asked to provide detailed information concerning their financial interests, consultant positions, and research grants and contracts, to permit evaluation of possible sources of conflict of interest.

The Department is seeking a broad geographic representation and has special interest in assuring that women, minority groups, and the physically handicapped and are adequately represented on advisory bodies and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and/or physically handicapped candidates.

Dated: June 12, 2001.

**John M. Eisenberg,**

*Director,*

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**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### Agency Information Collection Activities: Proposed Submission to the Office of Management and Budget (OMB) for Clearance; Comment Request; Reinstatement of Previously Approved Information Collection

**AGENCY:** Administration on Aging, HHS.

The Administration on Aging (AoA), Department of Health and Human Services, provides an opportunity for comment on the following proposal for the collection of information in compliance with the Paperwork Reduction Act (PRA; Pub. L. 96-511):

*Title of Information Collection:* Reporting Requirements for the Alzheimer's Disease Demonstration Grants to States Program and GPRA data.

*Type of Request:* Reinstatement of a previously approved collection for which approval has expired.

*Use:* Data on persons served, services provided, and program staff will be collected semi-annually from participants in the Alzheimer's Disease Demonstration Grants to States Program. Data will be used for program modification and evaluation, annual Department reports, and a final report to Congress as set forth by congressional statute.

*Frequency:* Semi-annually.

*Respondents:* Agencies of State Governments that have been designated by the governor as the sole applicant for the State and who have applied for a grant under this program.

*Estimated Number of Responses:* 50/year.

*Total Estimated Burden Hours:* 1,000/year.

*Additional Information or Comments:* The Administration on Aging plans to submit to the Office of Management and Budget for reinstatement of a previously approved collection for which approval has expired, for the Alzheimer's Disease Demonstration Grants to States Program, pursuant to requirements set forth by congressional statute. Written comments and recommendations for the proposed information collection should be sent within 60 days of the publication of this notice directly to the following address: Office of Program Development, Administration on Aging, Attention: Melanie Starns, 330 Independence Avenue, SW., Rm 4270, Washington, DC 20201.

Dated: June 18, 2001.

**Norman L. Thompson,**

*Acting Principal Deputy Assistant Secretary for Aging.*

[FR Doc. 01-15728 Filed 6-21-01; 8:45 am]

**BILLING CODE 4154-01-U**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Interest in Participating in the Selection of the Nonvoting Members of Industry Interests on Public Advisory Committees; Nonprescription Drugs Advisory Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is filling the position of nonvoting industry representative on the Nonprescription Drugs Advisory Committee. FDA requests that any industry organization, that is interested in participating in the selection of an appropriate nonvoting member of the Nonprescription Drugs Advisory Committee to represent industry, send a letter stating that interest to the FDA employee designated below within 30 days of the date of this notice. In addition, if individuals or organizations would like to nominate individuals to serve as the nonvoting industry representative, they may do so.

**DATES:** Letters of interest and nominations should be received on or before July 23, 2001.

**ADDRESSES:** All nominations for membership should be submitted to Sandra Titus (address below).

**FOR FURTHER INFORMATION CONTACT:** Sandra Titus, Advisors and Consultants Staff (HFD-21), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: tituss@cder.fda.gov.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Function**

The function of the committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

##### **II. Selection Procedure**

Any industry organization interested in participating in the selection of an appropriate nonvoting member of the

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.*

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## 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)).