

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SMB

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[Docket No. 01N-0219]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

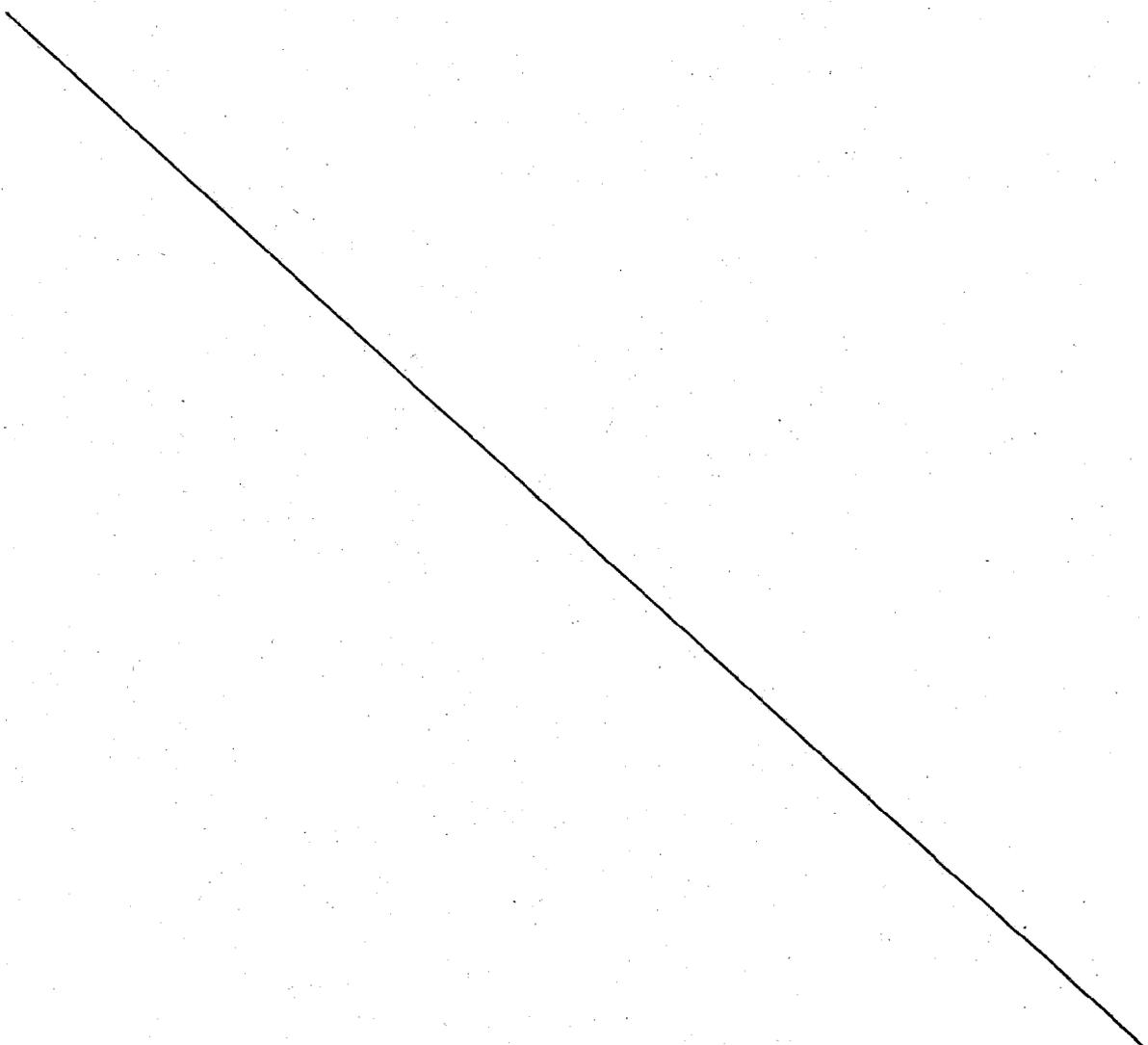
SUMMARY: The Food and Drug Administration (FDA) is withdrawing, without prejudice, approval of a new drug application (NDA) for Breokinase® (Urokinase for Injection) held by Serono, Inc., 100 Longwater Circle, Norwell, MA 02061. Serono, Inc., notified the agency in writing that it does not intend to 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market or export Breokinase® from the United States, and voluntarily requested that the approval of the application be withdrawn and thereby waived its opportunity for a hearing.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 [*insert date 30 days after date of publication in the Federal Register*].

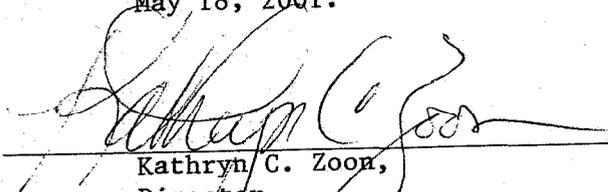
FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

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CFR 5.82), approval of the application listed in this document, and all amendments and supplements thereto, is hereby withdrawn, as of [*insert date 30 days after date of publication in the Federal Register*].



Dated: 5/18/01
May 18, 2001.


Kathryn C. Zoon,
Director,
Center for Biologics Evaluation and Research.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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