

**U.S. Food and Drug Administration**[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

FDA News

FOR IMMEDIATE RELEASE

May 14, 2008

Media Inquiries:

Peper Long, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

Manufacturer Removes Remaining Stocks of Trasylol *Access Limited to Investigational Use*

Background: On Nov. 5, 2007, the U.S. Food and Drug Administration announced that Bayer Pharmaceuticals Corp. agreed to an FDA-requested marketing suspension of Trasylol, a drug used to control bleeding during heart surgery. At that time, preliminary results from a Canadian study suggested an increased risk for death compared to two other drugs used to control bleeding.

Bayer HealthCare Pharmaceuticals Inc. has notified the FDA that the company will begin removing the remaining Trasylol stock from the U.S. market, most of which is in warehouses and hospital or physician's stock. The FDA will work with Bayer to ensure a smooth and complete process.

Under a limited use agreement, access to Trasylol is limited to investigational use of the drug according to the procedures described in a special treatment protocol. The protocol allows treatment for certain patients who are at increased risk of blood loss and transfusions during coronary artery bypass graft surgery and who have no acceptable alternative therapy. Physicians using Trasylol in this situation must also verify that the benefits of the drug clearly outweigh the risks for their patients.

FDA limits access to certain drugs to patients with serious or immediately life-threatening disease or conditions who lack other therapeutic options and may benefit from such therapies. This type of access requires the submission of a protocol, which is reviewed and approved by the agency. Bayer has agreed to provide Trasylol through this mechanism for the limited use described above.

Trasylol is an antifibrinolytic drug approved to reduce blood loss during surgery and the need for blood transfusion in certain patient undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. Antifibrinolytic drugs help slow the breakdown of blood clots and subsequent excessive bleeding.

Results from a randomized Canadian study that prompted last November's marketing suspension of Trasylol are expected to be published this week. The data contained in this article suggest that Trasylol appears to increase the risk for death compared to two other antifibrinolytic drugs used in the study.

The findings from this randomized study are similar to those from an observational study that was discussed at a September 2007 FDA advisory committee meeting. Based upon the data available at the time, the advisory committee recommended continued marketing of Trasylol. However, FDA requested the marketing suspension in the interest of patient safety based on the serious nature of the outcomes suggested in the preliminary data. The committee also advised that a large, randomized clinical study was needed to further assess Trasylol's safety compared to other drugs. This recently published Canadian study

helps address this need for additional information.

The FDA has not yet received full study data from the study's researchers at the Ottawa Health Research Institute but supports Bayer's decision to completely remove Trasylol from regular use in the U.S. market. FDA is also reviewing the available Canadian study data to reassess the currently active special treatment protocol that provides access to Trasylol.

FDA oversight requires comprehensive and thorough studies of a drug not only during the pre-market review phase but throughout the drug's life cycle. As studies and data on Trasylol emerged over the years, FDA actions included labeling changes, safety communications to physicians and other health care professionals, public discussion and review of study data at two Advisory Committee meetings, as well as close scrutiny of the ongoing studies.

The agency will consider a variety of study designs to support the review process for future antifibrinolytics, and will incorporate into these considerations information from the recently published Canadian study. FDA will continue to publicly disseminate safety information.

#

Additional Information

[Feb. 8, 2006—FDA Press Release on Public Health Advisory for Trasylol](#)

[Sep. 29, 2006—FDA Statement Regarding New Trasylol Data](#)

[Dec. 15, 2006—FDA Press Release Announcing Trasylol Label Changes](#)

[Oct. 25, 2007—FDA Early Communication on Trasylol Safety](#)

[Nov. 5, 2007—FDA Press Release Announcing Marketing Suspension of Trasylol](#)

[Treatment Use of an Investigational New Drug—21 Code of Federal Regulations](#)

#

[RSS Feed for FDA News Releases](#) [\[what is RSS?\]](#)

[Get free weekly updates](#) about FDA press releases, recalls, speeches, testimony and more.

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)