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## FDA NEWS RELEASE

**For Immediate Release:** August 16, 2010

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### **FDA Proposes Withdrawal of Low Blood Pressure Drug**

*Companies failed to provide evidence of clinical benefit of midodrine hydrochloride*

The U.S. Food and Drug Administration today proposed to withdraw approval of the drug **midodrine hydrochloride**, used to treat the low blood pressure condition orthostatic hypotension, because required post-approval studies that verify the clinical benefit of the drug have not been done.

**Patients who currently take this medication should not stop taking it and should consult their health care professional about other treatment options.**

The drug, marketed as ProAmatine by Shire Development Inc. and as a generic by others, was approved in 1996 under the FDA's accelerated approval regulations for drugs that treat serious or life-threatening diseases. That approval required that the manufacturer verify clinical benefit to patients through post-approval studies.

To date, neither the original manufacturer nor any generic manufacturer has demonstrated the drug's clinical benefit, for example, by showing that use of the drug improved a patient's ability to perform life activities.

Orthostatic hypotension is a condition in which patients are unable to maintain blood pressure in the upright position and, therefore, become dizzy or faint when they stand up.

Generic versions of the drug are made by Apotex Corp., Impax Laboratories Inc., Mylan Pharmaceuticals, Sandoz Inc., and Upsher-Smith Laboratories.

According to a database used by the FDA, about 100,000 patients in the United States filled prescriptions for brand or generic forms of midodrine in 2009.

The agency is working with the drug manufacturers to develop an expanded-access program to allow patients who currently receive the drug to continue to receive it. On a case-by-case basis, expanded-access programs allow the use of a drug outside of a clinical trial to treat patients with a serious or immediately life-threatening disease or a condition that has no comparable or satisfactory alternative treatment options.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222580.htm>

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