

September 8, 2010

Robert Temple, M.D.
Director
Office of Medical Policy
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Midodrine Hydrochloride

Dear Dr. Temple,

Please accept this letter of support for the Food and Drug Administration's decision to maintain approval for Midodrine Hydrochloride (Midodrine HCl). The undersigned physician organizations appreciate FDA's consideration of the negative implications of withdrawing approval for midodrine hydrochloride for patients—and urge you to continue to bear these in mind when considering a final determination on the medication in the coming months.. Recognizing the prerogative of the Food and Drug Administration (FDA) to withdraw approval from medications that do not meet established guidelines, we respectfully urge FDA to consider allowing the continued use of midodrine HCl indefinitely.

We appreciate that the associated drug manufacturers did not complete the necessary clinical studies as required as a stipulation of initial approval. Nonetheless, we underscore the invaluable role midodrine hydrochloride plays in treating a range of diseases and conditions, including cardiac, gastro-intestinal, and kidney diseases. The drug is important in the care of patients suffering from a host of illnesses related to hypotension.

As FDA has recognized, to deny physicians and their patients this treatment option without a viable alternative on the market would be a mistake. Although clinical data on midodrine hydrochloride is not currently available, the collective experience and expertise of the approximately 60,000 members of our organizations suggests this medication is necessary for preserving the public health.

Midodrine hydrochloride improves life for numerous patients suffering from a myriad of diseases. As the FDA decides on a final course of action, we respectfully urge the agency to keep this drug available to those patients for whom it is a medical necessity.

Thank you for your time and consideration. To discuss these comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

American Autonomic Society

American Society of Nephrology

American College of Cardiology

American Society of Pediatric Nephrology

American Society of Hypertension

Renal Physicians Association