



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

December 31, 2012

Frederik Defesche  
President  
Custo Pharm, Inc.  
2325 Camino Vida Roble  
Suite A  
Carlsbad, CA 92011

**FILE COPY**

Dear Mr. Defesche:

Your petition to the Food and Drug Administration requesting to designate Midodrine Hydrochloride Tablets, ANDA 076449 as the reference listed drug for the purpose of submitting an abbreviated new drug application, was received by this office on 12/31/2012. It was assigned docket number FDA-2013-P-0027/CP1, and it was filed on 12/31/2012. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega  
Administrative Proceedings Officer  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0027

ACK