DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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May 10, 2013

Kevin Barber, Ph.D., R.A.C., P.M.P.
Vice President, Regulatory Affairs
Watson Laboratories, Inc.
577 Chipeta Way
Salt Lake City, UT 84108-1222

Dear Dr. Barber:

Your petition to the Food and Drug Administration requesting FDA to take certain actions listed in the petition with respect to generic versions of RAPAFLO® (silodosin) Capsules, 4mg and 8mg in an Abbreviated New Drug Application ("ANDA"), in particular ANDA No. 204726 submitted by Sandoz Inc., was received by this office on 05/10/2013. It was assigned docket number FDA-2013-P-0574/CP1, and it was filed on 05/10/2013. 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)