DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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April 3, 2013

David Zuchero, M.S., J.D.
President
Chesapeake Regulatory Group, Inc.
6574 River Clyde Drive
Highland, MD 20777

Dear Mr. Zuchero:

Your petition to the Food and Drug Administration to designate the following approved drug products as the Reference Listed Drugs in order to allow the sponsors of future 505(j) applications to reference these products listed in the petition, was received by this office on 04/03/2013. It was assigned docket number FDA-2013-P-0408/CP1, and it was filed on 04/03/2013. 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)