DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 30, 2013

FILE COPY

Robert L. Florence
McGuireWoods LLP
1230 Peachtree Street, N.E.
Suite 2100
Atlanta, GA 30309-3534

Dear Mr. Florence:

Your petition to the Food and Drug Administration requesting the Agency to determine that Ropivacaine Hydrochloride Injection 2mg/mL (0.2%) with a new fill volume of 500 mL in an infusion bag is suitable for submission as an Abbreviated New Drug Application (ANDA), was received by this office on 09/26/2013. It was assigned docket number FDA-2013-P-1203/CP1, and it was filed on 09/26/2013. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)