DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 6, 2014

Rebecca L. Dandeker
Partner
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Ms. Dandeker:

Your petition to the Food and Drug Administration requesting the Agency to refrain from submitting the stated recommendation to HHS to reclassify Hydrocodone combination products that contain Hydrocodone Bitartrate in a strength that is lower than 5 mg in strength into schedule II, was received by this office on 12/27/2013. It was assigned docket number FDA-2013-P-1711/CP1, and it was filed on 1/6/2014. 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)