DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 25, 2014

David M. Fox, Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street N.W.
Washington, D.C. 20004

Dear Mr. Fox:

Your petition to the Food and Drug Administration requesting that FDA reconsider the determination that its products cobicistat (COBI) and elvitegravir (EVG) may not be granted five-year NCE exclusivity under the new statutory interpretation of the exclusivity provisions being adopted by FDA was received by this office on 03/24/2014. It was assigned docket number FDA-2013-P-0058, and it was filed on 3/25/2014. 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)