



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

January 8, 2013

David M. Fox, Esq.  
Hogan Lovells US LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004

Dear Mr. Fox:

Your petition to the Food and Drug Administration on behalf of Gilead Sciences, Inc. requesting to recognize 5-year exclusivity for each of the new active moieties in STRIBILD®, namely EVG and COBI, and make any necessary changes to FDA's Exclusivity Summary to reflect an interpretation of the governing statute and regulation that recognizes 5-year exclusivity for all active moieties, was received by this office on 1/8/2013. It was assigned docket number FDA-2013-P-0058/CP1, and it was filed on 1/8/2013. 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)

*FDA-2013-P-0058*

*ACK*