Docket

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JUL 0 5 2013

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

Re: Docket No. FDA-2013-P-0058

Dear Mr. Fox:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 8, 2013, and submitted on behalf of Gilead Sciences, Inc. Your petition requests that the Agency recognize 5-year exclusivity under sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act for each of the new active moieties in Stribild, and make any necessary conforming changes to affected agency documents to reflect an interpretation of the governing statute and regulations that recognizes 5-year exclusivity for all new active moieties.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research