Dockets

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUL 26 2013

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Theodore M. Sullivan, Esq.
Edward John Allera, Esq.
Buchanan Ingersoll & Rooney PC
1700 K Street, NW, Suite 300
Washington, DC 20006-3807

Re: Docket No. FDA-2013-P-0119

Dear Mr. Sullivan and Mr. Allera:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated January 29, 2013, and submitted on behalf of Ferring Pharmaceuticals, 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 (the FD&C Act) for the new active moiety in Prepopik, and stay any acceptance or approval of any abbreviated new drug application or new drug application submitted through the pathway described by section 505(b)(2) of the FD&C Act that references Prepopik until this request regarding the exclusivity period has been addressed.

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