FDA U.S. FOOD & DRUG ADMINISTRATION

Dr. Thomas F. Poché
Vice President and Assistant General Counsel
Allergan Holdings Unlimited Company
5 Giralda Farms
Madison, NJ 07940

Re: Docket No. FDA-2019-P-2537

NOV 18 2019

Dear Dr. Thomas Poché:

I am writing to inform you that the Food and Drug Administration (FDA or the agency) has not yet resolved the issues raised in your citizen petition received on May 23, 2019. Your petition requests that the Agency refuse to receive or approve any abbreviated new drug application (ANDA) referencing any strength of Allergan's Viberzi (eluxadoline) tablets that does not contain scientifically appropriate data demonstrating bioequivalence (BE). Additionally, your petition requests that the Agency publish and receive public comment on a guidance to address the criteria and scientific rationale the Agency applies in determining whether a generic drug raises abuse or scheduling issues.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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