DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 24, 2019

Thomas F. Poche, Ph.D.
Vice President & Assistant General Counsel
Allergan Holding Company
5 Giralda Farms
Madison, NJ 07940

Sent via email to: thomas.poche@allergan.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug refuse to receive, and refuse to approve, any abbreviated new drug application("ANDA") that refers to VIBERZI and that does not include comparative clinical endpoint data to demonstrate that the ANDA product is bioequivalent to VIBERZI (a locally-acting drug product, with low bioavailability, and highly variable pharmacokinetics); Refuse to receive, and refuse to approve, any ANDA that refers to VlBERZI and that does not include scientific and clinical data that demonstrate either (1) that the active ingredient is the same polymorphic form (Form Alpha) as the active ingredient inVIBERZI, or (2) that the active ingredient is a different polymorphic form and the formulated product does not have greater abuse potential than VIBERZI; Publish an updated and revised draft guidance document, consistent with recent and current guidances for other locally acting drugs, and solicit comments, to provide recommendations with respect to analyses for the approval of a generic version of VIBERZI• (eluxadoline) tablets ("VIBERZI") that requires clinical endpoint testing of this locally-acting, poorly permeable drug product; and Publish and receive public comment concerning the criteria and scientific rationale that FDA applies when considering whether a generic oral drug may raise abuse or scheduling issues (whether or not the product has chemistry extraction study information in the label) and therefore warrants review by the FDA Controlled Substances Staff (CSS), including issues relating to "sameness" criteria with respect to abuse potential, and abuse potential testing requirements for innovator and generic drugs,was received by this office on 05/23/2019.

It was assigned docket number FDA-2019-P-2537. 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 Malvin Digitally signed by Karen Malvin Date: 2019.05.24 11:37:32 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)