



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 1, 2020

Kristi Norris, PhD
Vice President, Regulatory Strategy
Camargo Pharmaceutical Services, LLC
800 Taylor Street, Mill No. 1, Suite 101
Durham, NC 27701

Sent via email to: knorris@camargopharma.com and robert@centerlab.com.tw

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to make a determination that the discontinued formulations of CALAN (verapamil hydrochloride) 40, 80, 120, and 160 mg oral tablets (NDA 018817) from Pfizer Inc were not discontinued due to safety or efficacy reasons was received by this office on 11/30/2020.

It was assigned docket number FDA-2020-P-2245. 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,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)