DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 19, 2019

Soma Raju, Ph.D
Hetero Labs Limited
1035 Centennial Avenue
Piscataway, NJ 08854

Sent via email to: somaraju@heterousa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether the drug product Mexitil® (Mexiletine Hydrochloride) has been voluntarily withdrawn from sale for safety or efficacy reasons was received by this office on 06/19/2019.

It was assigned docket number FDA-2019-P-2982. 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: 2019.06.20 13:22:02 -04'00'

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