DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 11, 2022

Kurt R. Karst
Hyman, Phelps & McNamara, PC
700 Thirteenth Street, NW Suite 1200
Washington, DC 20005-5929

Sent via email to: Kkarst@hpm.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration to determine whether ENDEP (amitriptyline HCl) Oral Concentrate, 40 mg/mL, approved under Abbreviated New Drug Application (ANDA) number 085749, held by Hoffmann-La Roche Inc, has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 01/11/2022.

It was assigned docket number FDA-2022-P-0068. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby
Digitally signed by Dynna Gorham-Bigby
Date: 2022.01.11 16:00:34 -05'00'

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