



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

September 23, 2019

Ravi Rangasami, MBR  
Director  
Hibrow Healthcare, LLC  
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*Sent via email to: [ravi.r@hibrowhealthcare.com](mailto:ravi.r@hibrowhealthcare.com)*

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA determine that Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL were not voluntarily withdrawn for safety and efficacy reasons was received by this office on 09/23/2019.

It was assigned docket number FDA-2019-P-4424. 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 Specialist  
Dockets Management Staff  
FDA/Office of Operations (OO)