



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 18, 2020

Frank D. Rodriguez
Windels Marx Lane & Mittendorf, LLP
One Giralda Farms
Madison, NJ 07940

Sent by email to: frodriguez@windelsmarx.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate ANDA 088864 (Dextromethorphan Hydrobromide and Promethazine Hydrochloride Oral Syrup, 15 mg/5 mL; 6.25 mg/5 mL) held by Wockhardt Bio AG ("Workhardt") as a RS for purposes of FDA evaluation of ANDAs for Dextromethorphan Hydrobromide and Promethazine Hydrochloride Oral Syrup, 15 mg/5 mL; 6.25 mg/5 mL was received by this office on 08/17/2020.

It was assigned docket number FDA-2020-P-1771. 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 and 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)