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November 18, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

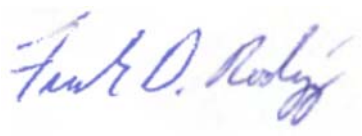
Citizen Petition – Withdrawal Request

Re: FDA Docket No. FDA-2020-P-1771-0001

Dear Sir/ Madam,

The undersigned ('Petitioner') has become aware of FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," in which FDA states that applicants may submit controlled correspondence to ask FDA to designate a new reference listed drug or select a reference standard ("RS"). Because the controlled correspondence pathway is now available, Petitioner requests withdrawal of the above-referenced citizen petition requesting that, due to market unavailability of the current RS, FDA designate as a new RS Dextromethorphan Hydrobromide and Promethazine Hydrochloride Oral Syrup, 15 mg/5 mL; 6.25 mg/5 mL, approved under abbreviated new drug application (ANDA) 088864 and held by Wockhardt Bio AG. As such, a formal response to Docket No. FDA-2020-P-1771 is no longer necessary.

Sincerely,



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