



Ravi Rangasami
Director
Hibrow Healthcare LLC
601 Carlson Parkway, Suite 1050
Minnetonka, MN 55305

Re: Docket No. FDA-2019-P-4424

4/21/2020

Dear Mr. Rangasami:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on September 23, 2019. Your petition requests that the Agency designate an alternate reference standard for Doxepin Hydrochloride Oral Concentrate Eq 10 mg base/mL, in the active section of the Orange Book for the purpose of conducting bioequivalence studies to compile and submit an abbreviated new drug application for this product.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

