



Saeed Qureshi
Pharmacomechanics
56 Gleeson Way
Ottawa, ON K2J 4Y7 CANADA

MAR 29 2019

Re: Docket No. FDA-2018-P-3742

Dear Dr. Qureshi:

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 October 1, 2018. Your petition requests that the Agency withdraw FDA guidance documents and related recommendations concerning assessments of drug dissolution characteristics of the pharmaceutical products such as tablet and capsule.

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 J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research