



Shane Ririe
Chief Financial Officer
grBiosystems Inc.
138 E 12300 S, Suite C-435
Draper, UT 84020

September 4, 2020

Re: Docket No. FDA-2020-P-0983

Dear Mr. Ririe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 27, 2020. Your petition requests that the Agency permit grBiosystems Inc. to proceed with an alternative to the testing procedure specified for fluoride dentifrices in 21 CFR 355.70, as provided in 355.70(c).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

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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Date: 2020.09.03 16:10:37 -04'00'

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