



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 28, 2020

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

Sent via email to: sririe@grbiosystems.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA permission to proceed with an alternative fluoride study to the requirement found in Section 355.70(a) and (c) was received by this office on 02/27/2020.

It has been assigned docket number FDA-2020-P-0983. 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 in that it 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)