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

May 9, 2023

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

Dear Mr. Ririe:

This letter responds to your citizen petition received on February 27, 2020 (Petition). Your Petition requests "permission" from the Food and Drug Administration (FDA or the Agency) "to proceed with an alternative fluoride study to the requirement found in sec. 355.70(a)" (Petition at 1). Specifically, you "request permission to proceed with the Featherstone laboratory pH cycling model."[1] (Id.). You note that you are "developing toothpaste using stannous fluoride as an active ingredient." As your Petition does not identify a specific formulation for which you would use this alternative testing method, we understand your request to generally apply to any "toothpaste using stannous fluoride as an active ingredient" in accordance with the monograph for anticaries drug products.

We have carefully considered your Petition. For the reasons described below, your Petition is denied.

While your Petition was pending with the Agency, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted,[2] adding section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which changed certain aspects of the legal framework for nonprescription drug products marketed without an approved application.[3] As a result of the enactment of section 505G, the process by which the Agency evaluates a request for an addition to or revision of an over-the-counter (OTC) monograph has changed. In particular, the addition of section 505G to the FD&C Act has changed the mechanism for establishing, amending, or withdrawing OTC monographs from a rulemaking process to an administrative order process.

[1] You include the following citation for this model: Stookey, George K. "The Featherstone laboratory pH cycling model: A prospective, multi-site validation exercise." American Journal of Dentistry 24.5 (2011): 322.
[2] Public Law No. 116-136, 134 Stat. 281 (March 27, 2020).
[3] We note that your Petition references the final monograph for OTC anticaries drug products at 21 CFR part 355. The final order for OTC anticaries drug products, Final Administrative Order OTC000034 Over-the-Counter Monograph M021: Anticaries Drug Products for Over-the-Counter Human Use available via the OTC Monographs@FDA portal at https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm, incorporates the requirements of the final monograph for OTC anticaries drug products issued under part 330, as codified in part 355 as of March 27, 2020, with technical amendments.

Under section 505G(b) of the FD&C Act, FDA may, on its own initiative or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs is determined to be not subject to section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)) and generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). Under section 505G(b)(5) of the FD&C Act, a requestor seeking that the Secretary issue such an administrative order "shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary." As described in section 744L(7) of the FD&C Act (21 U.S.C. 379j-71(7)), such a request is termed an *OTC monograph order request* (OMOR). A "requestor" is broadly defined in section 505G(q)(3) as "any person or group of persons marketing, manufacturing, processing, or developing a drug."

Because you are a *requestor*, as defined in section 505G(q)(3) of the FD&C Act and your Petition's request to use alternative testing procedures for stannous fluoride toothpaste products is a type of relief that could be sought under an OMOR (see 505G(b)(5) of the FD&C Act), the citizen petition process is no longer the appropriate procedure for addressing your request, and your Petition is denied. Please note that information about the OMOR process is available on FDA's website[4] should you pursue that process for your request.[5]

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2023.05.05 14:49:26 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[4] See *OTC Drug Review Process | OTC Drug Monographs*, available at https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs; see also *Frequently Asked Questions* available via the OTC Monographs@FDA portal at https://dps.fda.gov/omuf/faqs.

[5] If you are considering submitting an OMOR, we encourage you to request a Type Y pre-OMOR meeting to discuss your OTC monograph development program prior to submitting the OMOR. See FDA Guidance for Industry *Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs*, available at https://www.fda.gov/media/155864/download.