DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 3, 2019

Janelle Delk, Director
Global Regulator Affairs
IQVIA RDS Inc.
1801 Rockville Pike, Suite 300
Rockville, MD 20852-1633

Sent via email to: Janelle.Delk@iqvia.com

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting to designate a suitable alternative reference standard to enable your client to proceed with the development of the genetic product was received by this office on 08/30/2019.

It was assigned docket number FDA-2019-P-4101. 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
Digitally signed by Dynna Bigby
Date: 2019.09.03 12:37:06 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Dockets Management Staff
FDA/Office of Operations (OO)