

From: Ramachandran, Girish
Sent: Wednesday, October 24, 2018 10:24 AM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: BLA 125563 Information Request

Dear Ms. Mayer,

We have reviewed Amendment 39 (SN 38 submitted on August 31, 2018). The following comments pertain to document Q_0268418 "Design Specification for D-antigen (b) (4) Calculation Program for Polio":

(b) (4)

[Redacted content]

Could you please send us your responses by October 31st?

Thanks,

Girish

Girish Ramachandran, Ph.D.
Primary Regulatory Reviewer/Regulatory Project Manager

FDA/CBER/OVRR/DVRPA

10903 New Hampshire Ave.

WO71

Silver Spring, MD 20993-0002

Phone- 301-796-2640

FAX-301-595-1124

Girish.Ramachandran@fda.hhs.gov

