

From: Ramachandran, Girish
Sent: Thursday, November 01, 2018 11:44 AM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: BLA125563 Information Request
Importance: High

Dear Ms. Mayer,

The following is in reference to your 26 October 2018 (Sequence 46, Amendment 44) response to Question 6 of our information request dated 15 October 2018:

Please provide additional support that the currently proposed acceptance criteria for the poliovirus minimum potency at release (b) (4), and (b) (4) D-antigen units/dose for types 1, 2, and 3, respectively) for PR5I is, as stated in the BLA, "as immunogenic as the currently licensed component vaccine control(s) (i.e., PENTACELTM and RECOMBIVAX HBTM in the US, and INFANRIXTM hexa in Europe)". One such approach would be to compare the D-Antigen content of representative Pentacel and PR5I lots tested in parallel in the same assay and calculated using the (b) (4) method. The number of lots tested should be adequate to allow statistical analyses and to support a potential adjustment of the release criteria for the IPV component of PR5I if necessary. Please commit to submitting such supportive data within one year of approval of the BLA for PR5I (Vaxelis).

Thanks,

Girish

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