

From: Krissy.Carrington@sanofipasteur.com
To: [Hoffman, Kelsy](#)
Cc: [Rivers, Katie](#)
Subject: RE: BLA 125563/0 Information Request
Date: Monday, July 13, 2015 4:49:57 PM

Dear Kelsy,
I acknowledge receipt of this request. Kind regards,
Krissy

From: Hoffman, Kelsy [mailto:Kelsy.Hoffman@fda.hhs.gov]
Sent: Monday, July 13, 2015 3:27 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Rivers, Katie
Subject: BLA 125563/0 Information Request

Ms. Carrington,

We have the following Information Request for BLA 125563/0 regarding serious adverse events (SAEs):

Please provide tables that include SAEs recorded within 15 and 30 days after administration of any dose of PR5I and control for:

- a) all studies (separately), if not already provided;
- b) studies 005 and 006 (pooled);
- c) studies 003, 004, 007, and 008 (pooled).

We anticipate that these tables will be similar to Table 2 that is provided in the proposed package insert. Please let me know if you have any questions.

Thank you,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Primary Reviewer/Regulatory Project Manager
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