

11/24/2015

To: Brenda Baldwin, DVRPA

From: Marina Zaitseva, DVP

Through: Hana Golding, DVP

Through: Jerry Weir, DVP

Re: Review of the response from Novartis to Information Request sent by FDA on August 19 2015 submitted in Amendment 20 to BLA 125510.

CBER requested information regarding the type of the (b) (4) that are used for storage of the sterile filtered MF59C.1 and for shipping of MF59C.1 adjuvant (b) (4) from the (b) (4) facility to the (b) (4) facility (3.2.P.3.3.2.1) and conformation that these (b) (4) are the same (b) (4) manufactured by (b) (4) (3.2.S.6).

In the response to this question in Amendment 20, Novartis confirmed that that (b) (4) used for the storage of the sterile filtered MF59C.1 are the same ones used for the storage of MF59 adjuvant (b) (4) shipped from (b) (4).

The response is acceptable and it means that there is no need to perform new leachable study for the (b) (4) storage containers as this study was performed and the data was described for (b) (4) used to store MF59C.1 (b) (4) Adjuvant manufactured at (b) (4) facility.

In addition, Amendment 20 provides a Certificate of Analysis for (b) (4) used for storage of the manufactured MF59C.1 adjuvant (b) (4)

All information is acceptable.