

Valencia, Iliana

From: Valencia, Iliana
Sent: Tuesday, February 10, 2015 5:38 PM
To: Allison Kennedy (akennedy@ebsi.com)
Subject: STN 125562_0 Cangene AIGIV PMC#2

Dear Ms. Kennedy,

FDA reviewed your proposed modifications of Post Market Commitment (PMC) in your *response to FDA information Requests dated January 13, 2015 and January 15, 2015*, and provides the following feedback:

FDA agrees with the modifications of the first and third PMC, but disagrees with the modifications on the second PMC regarding the validation of (b) (4) method.

In your validation report MV_0227_rep_v2, the validated range of detection is from (b) (4), i.e., the lower limit of quantitation (LLOQ) of the assay is (b) (4) and upper limit of quantitation (ULOQ) of the assay is (b) (4). The data shown in table 1:1 Acceptance Criteria and Summary of Results indicated that the spike assays with concentration from (b) (4) passed the test with acceptance accuracy, but not the ones with concentration below (b) (4) or above (b) (4) has a (b) (4) acceptance criterion).

FDA agrees that use of either (b) (4) as reference reagent is acceptable in this assay. But the LLOQ will have to be validated below (b) (4) using the current international standard (b) (4). Please also note that this requirement of LLOQ to be (b) (4) is the minimum requirement for this assay.

Thereby FDA has modified the PMC as follows:

PMC #2: Cangene commits to (b) (4)

The validation report will be submitted to CBER as a CBE-30 by March 25, 2016.

Please submit a response as an amendment to the file indicating your commitment to the modified language for PMC#2 by February 18, 2015.

Sincerely,

Iliana Valencia, MS
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IOD
240-402-8444
202-591-6054
iliana.valencia@fda.hhs.gov

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