
From: Eichelberger, Maryna
Sent: Friday, February 09, 2018 11:51 AM
To: Francis, Kori <Kori.Francis@fda.hhs.gov>
Cc: Bhattacharyya, Lokesh <Lokesh.Bhattacharyya@fda.hhs.gov>
Subject: RE: SBRA language for STN: 125588, 125589, (b) (4)

Hi Kori,

This is the language that our Office agreed is suitable for these products. I concur with the statement below.

Thanks,

Maryna

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From: Francis, Kori
Sent: Friday, February 09, 2018 11:46 AM
To: Eichelberger, Maryna <Maryna.Eichelberger@fda.hhs.gov>
Cc: Bhattacharyya, Lokesh <Lokesh.Bhattacharyya@fda.hhs.gov>
Subject: SBRA language for STN: 125588, 125589, (b) (4)

Hello Maryna

As discussed previously, there are four additional products that will require a statement for their respective SBRA's. Once again I am seeking your concurrence to use the same language for each of the STNs listed above. After you concur, I will forward the wording to each chairperson and the DETTD coordinator. Thanks, in advance.

3.2 CBER Lot Release

The lot release protocol template was submitted to CBER for review and found to be acceptable after revisions. A lot release testing plan was developed by CBER and will be used for routine lot release.