**From:** Thompson, Edward
**Sent:** Wednesday, March 25, 2015 3:18 PM
**To:** 'Steve McGregor (smcgregor@ebsi.com)'
**Subject:** Reference BL 125426/0

**Contacts:** Steve McGregor

Dear Steve,

Please note the following communication from the FDA for your BL 125426/0 application:

As a response to the Agency Information Request from 4 March, 2015, you have reported in BL STN 125426/0, Amendment 61, Sequence 60 of the NIBSC study, that the monitoring of activity for IXINITY has been assessed at 17 laboratories using routine assays including the one-stage clotting assay with multiple reagents (b)(4) and routine reagents at each test site) and the (b)(4) assay using two standard kits. Based on the data, we agree that at this point that a field study is unnecessary. We may re-visit this decision in the future if the data suggests that such study and comparison will be beneficial. Additionally, the Package Insert should contain information on the variability of test results due to differences in assay reagents and reference standards.

Please send me a message if additional clarification is required.

Thanks,
Ed

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