

# Teleconference, June 22, 2012 - Ducord

## 125407/0 teleconference minutes

Friday, June 22, 2012 4:50 PM

**Duke:** Amanda Parrish, Ph.D, Bruce Burnett, Ph.D.;

**FDA:** Wei, Cheng-Hong; Gavin, Denise K

**Regarding:** BLA 125407 and CD34 Validation Question

**DUKE:** We were wondering if it would be acceptable to *remove* the information that was included here as part of Amendment 008 in response to requests for information (~250 pages). If you agree, we would not plan to resubmit the manufacturer's information, the QC data, etc. The extra information requested as part of review would not be printed and included again as part of Amendment 009. Thus, the new CD34 validation section (3.2.S.4.3.10) would only include the relevant, final validation reports and protocol. Can you confirm if this will be acceptable?

**FDA response:** No, it would not be acceptable to remove parts of the BLA that have previously been submitted for review purposes. Since we have reviewed this information it should be retained in the record. However, it will NOT be necessary to resubmit the additional information provided in Am 008 (e.g. manufacturer's information, QC results, instrument cross checks, etc which were put into section 3.2.S.4.3.10, which is supposed to house the CD34 validation; or the point-by-point responses to these questions which was included behind the cover letter for amendment [008]). We recommend that you simply refer to the additional information previously submitted in amendment Am 008, Section 3.2.S.4.3.10. as supportive information for the validation protocol when you submit the completed CD34 validation study reports and protocol in am 009.

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