

RECORD OF TELEPHONE CONVERSATION

Submission Type: NDA Submission ID: 125552/0 Office: OCTGT

Product:

Cord Blood Sterile Collection Bags with anticoagulant CPD

Applicant:

Macopharma

Telecon Date/Time: 20-November-2014/12:00 PM Initiated by FDA? Yes

Telephone Number: 866-906-9888

Communication Category(ies):

Product Information

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Telecon Summary:

Product Information

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Telecon Body

- a. Your (b) (4) data from the MSC1206DU version of the MacoProductions CB collection kit indicated that the collection bag must weigh (b) (4). Please clarify what part of this weight is cord blood.
- b. On page 3 of Vol 8, you state that: "Macopharma is seeking approval of the following two configurations. MSC1207DD is the collection set which will be provided for sale for customers in the United States" It appears the MSC1208DD configuration will not be marketed in the US. Please comment.

- c. Please clarify the following discrepancies:
 - i. Table 1 (Vol 8, page 6) identifies the MSC1207DD as having a collection volume of 200 ml and containing 21 ml + 8 ml CPD. This information conflicts with description of this configuration in Vol 1 page 1, Vol 8 page 3 and elsewhere, which describe this configuration as having 27 ml + 8 ml CPD. Please clarify.
 - ii. Although, Table 1 (Vol 8 page 6) identifies the major differences in the various configurations, MSC1208DD is not listed.
- d. Based on the information you have provided, FDA recommends revising the Indications for Use as follows:
 - i. Remove the statement “A minimum collection volume for CB has not been established. Collections below 40 ml should be tested for acceptable quality parameters as per Facility SOPs”.
 - ii. Based on the cited data please add the following statement to your Indications for Use: If the collection volume is less than 60 ml, the unit should be processed within 24 hours of collection.