

## Definition of Product

The intention of this appendix is to define the term **product**, and provide several examples of infusions using single and multiple products. This appendix will also provide direction with regard to reporting product infusion on the CIBMTR Infusion Form 2006.

**The Infusion Form 2006 must be submitted for each product.** In order for a Form 2006 to become due in the FormsNet™2 application, each product must be reported as a separate instance (including any supplemental cells given prior to clinical day 0) on the Pre-TED Form 2400. If the patient received multiple products of the same type (e.g. multiple PBSC products), the transplant center must contact the center's liaison to request an additional Form 2006 in FormsNet™2. Additionally, whenever multiple products are reported on the Comprehensive Report Forms, the transplant center must also contact the liaison to request additional Form 2006s in FormsNet™2.

### Single Product vs. Multiple Products

**Single Product:** For the purposes of this manual, the CIBMTR defines a *single product* (i.e., stem cell product) as **cells collected from a single donor using the same mobilization cycle and collection method regardless of the number of collection days.**

**If a *single* product is infused, then complete a *single* (i.e., one) Form 2006.** For more information, see the example below and Table 2 on page two of this document.

**Example 1 – multiple bags:** GCSF-stimulated donor had two PBSC collections on subsequent days. The products collected over the two days were divided into four bags. Although the product is contained in multiple bags, this collection is considered a single product, as there was no change in mobilization technique or collection method. Therefore, one Form 2006 should be submitted.

**Multiple Products:** For the purposes of this manual, the CIBMTR defines *multiple products* as **cells collected using more than one donor, mobilization technique, and/or collection method.** For more information, see Table 2 on page two of this document.

**If a *multiple* products are infused, then *multiple* (i.e., two or more) Form 2006s must be completed.** For more information, see the examples below and Table 2 on page two of this document.

**Example 2 – double cord blood units:** A recipient receives an infusion of two cord blood units. Two Form 2006s must be submitted as each cord blood unit is from a different donor.

**Example 3 – multiple collection methods:** GCSF-stimulated donor had a PBSC collection and the product was cryopreserved. One month later, the donor had a marrow collection and both products were infused at the time of transplant. Two Form 2006s must be submitted as these products were collected using two different methods.

**Example 4 – change in mobilization:** GCSF-stimulated donor had a PBSC collection, but cell count was poor. GM-CSF was added and the donor was recollected. Each collection is considered a separate product due to the change in mobilization. Therefore, a Form 2006 is due for the GCSF-stimulated cells and a second Form 2006 is due for the GM-CSF-stimulated cells.

**Example 5 – re-mobilization:** GCSF-stimulated donor had a PBSC collection, but cell count was poor. The donor was re-mobilized with GCSF and a second PBSC collection was performed. Each collection is considered a separate product due to the re-mobilization of the recipient.

**Table 2. Single Product vs. Multiple Products**

<b>Definition:</b>	<b>Number of Infusion Form 2006s Required:</b>
<p><b>Single Product</b> All of the following criteria must be met:</p> <ul style="list-style-type: none"> <li>• Single donor/cell source</li> <li>• Single mobilization method</li> <li>• Single collection method</li> </ul>	One
<p><b>Multiple Products</b> One or more of the following criteria must be met:</p> <ul style="list-style-type: none"> <li>• Multiple donors/cell sources</li> <li>• Multiple mobilization methods</li> <li>• Multiple collection methods</li> </ul>	Multiple – one to represent each donor/cell source, mobilization method, and/or collection method