

[October 22, 2007](#)

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[Commenter: Michael Linenberger, MD, Chair, ASFA Hematopoietic Progenitor Cell Donor Subcommittee](#)

Deleted: To: Christine Fernandez-Roig, RN, BSN, President, American Society for Apheresis

From

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Re: **FDA Docket No. 2007D-0290, CBER 20079. Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)**

[The American Society for Apheresis \(ASFA\) is the largest North American professional organization of physicians, scientists, nurses and technologists devoted to the field of donor and therapeutic apheresis.](#)

[As Chair of ASFA Hematopoietic Progenitor Cell Donor Subcommittee of the Apheresis Applications Committee, I am pleased to submit official ASFA comments on the FDA Draft Guidance for Industry, "Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells \(PBSCs\)" released in July 2007.](#)

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This [Guidance](#) points out that cell selection devices that prepare autologous, minimally manipulated PBSCs at the point of care for direct re-administration meet the definition of a medical device as defined in section 210(h) and are subject to the FDA medical device regulations. However, establishments that use an approved or cleared device to minimally manipulate PBSCs prior to implanting into the same individual during the same surgical procedure **meet the exception from requirements in Title 21 CFR 1271**. Title 21 CFR 1271 qualifies PBSCs as human cells, tissues, cellular or tissue-based products (HCT/P's) and outlines the regulations for establishment registration, donor eligibility, current good tissue practices (cGTPs), inspection and enforcement of requirements for HCT/Ps. In addition, if the PBSCs processed at the clinical site with the approved device meet five conditions, which include: (a) autologous use; (b) minimally manipulated; (c) the device is limited to recovery of autologous cells without other manufacturing; (d) the cells are not stored or shipped and (e) the device and selection are used at the clinical site where the cells are directly administered [i.e. at the point of care], the FDA **would not require the submission of an IND and BLA for the product**.

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One concern with this [Guidance](#) is that the "point of care" designation can be very loosely interpreted and may allow procurement and processing of PBSCs within inadequate facilities or under suboptimal circumstances that could compromise donor and/or product safety. The donor eligibility and product labeling requirements under 21 CFR 1271 and the facility and product oversight for PBSCs processed under IND could be bypassed. This might occur when PBSCs are collected, selected and reinfused in a medical clinic, hospital environment or research facility that is not accredited by agencies such as AABB or Foundation for the Accreditation of Cellular Therapy (FACT). Although medical monitoring in these settings may be satisfactory, practices and policies regarding product handling and processing may not be in place to minimize the risk of product contamination.

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A second concern is that autologous PBSCs that are processed with approved devices at the point of care may be intended for non-homologous use (e.g. reinfusion or injection to regenerate cardiac muscle, neural tissue or other organs/tissues). Such activities would, again, not incur FDA oversight by either 21 CFR 1271 regulations or IND submission. Because the non-homologous use of PBSCs for such applications is still highly experimental, we feel that FDA oversight of establishments that process PBSCs for these purposes is an important and prudent safeguard to ensure donor and product safety.