

August 25, 2010
(REVISED May 2016)

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

USAN (de-145)	CENPLACEL-L
PRONUNCIATION	sen' pla sel
THERAPEUTIC CLAIM	Treatment of immune-mediated and vascular diseases.

CHEMICAL DESCRIPTION

The active cellular product is the same for both PDA-001 and PDA-002 formulations of the product, however the concentrations of the various constituents differs.

PDA-001 contains cells at a concentration of $7.5 \pm 1.5 \times 10^6$ cells/mL frozen in solution containing 5.5% (weight/volume) Dextran-40, 10% (weight/volume) human serum albumin (HSA), and 5% (volume/volume) dimethyl sulfoxide (DMSO).

PDA-002 contains cells at a concentration of $0.67 \pm 0.20 \times 10^6$ cells/mL, $2.2 \pm 0.7 \times 10^6$ cells/mL, or $6.7 \pm 2.0 \times 10^6$ cells/mL frozen in solution containing 5.75% (weight/volume) Dextran-40, 10% (weight/volume) human serum albumin (HSA), and 2.5% (volume/volume) dimethyl sulfoxide (DMSO).

SPONSOR	Celgene Cellular Therapeutics
CODE DESIGNATION	PDA-001, PDA-002

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