Date: November 11, 2008

To: AABB Institutional Members

From: Doug Padley, MT(ASCP)
Chair, Cellular Therapy Standards Program Unit

Eduardo Nunes
Director, Standards Development, AABB

Re: Errata Sheet for *Standards for Cellular Therapy Product Services*, 3rd edition

Please note that the following error has been identified in the *Standards for Cellular Therapy Product Services*, 3rd edition:

Reference Standard 5.9.1B – Biohazard and Warning Labels
As published in the 3rd edition of *Standards for Cellular Therapy Product Services,* Reference Standard 5.9.1B, which addresses biohazard and warning labels, contains several printing errors.

As published, the reference standard inadvertently retains requirements from the 2nd edition of *CT Standards* which the Cellular Therapy Standards Program Unit intended for deletion. These errors affect product labeling for autologous donors.

Specifically, the CT SPU did not intend to require that autologous products be labeled with the phrase "Not Evaluated for Infectious Substances" if the facility performs screening and testing of autologous donors.

Similarly, the CT SPU did not intend to require that any autologous products be labeled with the phrase "WARNING: Advise Patient of Communicable Disease Risks".

Reference Standard 5.9.1B appears on the next page as intended by the CT SPU. Please note that the necessary changes are marked in this version and indicated by arrows.

Reference Standard 5.9.1B—Biohazard and Warning Labels											
			Status				Product Labels				
		Title 21 CFR Citation	All Donor Screening and Testing Completed	Abnormal Results of Donor Screening	Abnormal Results of Donor Testing	Urgent Medical Need	Biohazard Legend [per 21 CFR 1271.3(h)]	For Autologous Use Only	Not Evaluated for Infectious Substances	WARNING: Advise Patient of Communicable Disease Risks	WARNING: Reactive Test Results for (name of disease agent or disease)
Donor Eligibility Determination Required [21 CFR 1271.45(b)]											
1	Allogeneic donors with incomplete donor eligibility determination[2,3]	1271.60	No	No	No	Yes			X	X	
2	Allogeneic donors found ineligible										
	A first-degree or second-degree blood relative[4]	1271.65(b)(1)(i)	Yes	No/Yes	Yes	N/A	X			X	X
	A first-degree or second-degree blood relative[4]	1271.65(b)(1)(i)	Yes	Yes	No	N/A	X			X	
	Unrelated donor	1271.65(b)(1)(iii)	Yes	No/Yes	Yes	Yes	X			X	X
	Unrelated donor	1271.65(b)(1)(iii)	Yes	Yes	No	Yes	X			X	
Donor Eligibility Determination Not Required [21 CFR 1271.90(a)]											
3	Autologous donors[5]	1271.90(a)(b)									
	Autologous donor	1271.90(a)(1)(2)	No	No	No	N/A		X	X	~~X~~ ←	
	Autologous donor	1271.90(b)(1)(3)	Yes	No/Yes	Yes	N/A	X	X	~~X~~ ←		X
	Autologous donor	1271.90(b)(1)(3)	Yes	Yes	No	N/A	X	X	~~X~~ ←		

[1]At press time, this table, which is also contained in the *Circular of Information for Cellular Therapy Products* and the *FACT-JACIE International Standards For Cellular Therapy Product Collection, Processing, and Administration*, was undergoing revision. The updated table can be found in the most current *Circular of Information for Cellular Therapy Products*, available on the AABB Web site (www.aabb.org).

[2]The donor eligibility must be finalized during or after the use of the cellular therapy product. The results must be communicated to the treating physician [21 CFR 1271.60(d)(4)].

[3]Abnormal results of any screening or testing requires labeling as in item 2 of this table (21 CFR 1271.65 applies).

[4]Notification of the recipient's and donor's physicians of abnormal screening and/or testing results is required.

[5]Any abnormal donor screening or testing results (even though screening is not required for this group of donors) require appropriate labeling [21 CFR 1271.90(b)].

[6]21 CFR 1271.90 (b)(3)

N/A = not applicable