Food and Drug Administration, HHS

§ 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?

(a) Quarantine. You must keep an HCT/P in quarantine, as defined in §1271.3(q), until completion of the donor-eligibility determination required by §1271.50. You must quarantine semen from anonymous donors until the retesting required under §1271.85(d) is complete.

d) Identification of HCT/Ps in quarantine. You must clearly identify as quarantined an HCT/P that is in quarantine pending completion of a donor-eligibility determination. The quarantined HCT/P must be easily distinguishable from HCT/Ps that are available for release and distribution.

(c) Shipping of HCT/Ps in quarantine. If you ship an HCT/P before completion of the donor-eligibility determination, you must keep it in quarantine during shipment. The HCT/P must be accompanied by records:

(1) Identifying the donor (e.g., by a distinct identification code affixed to the HCT/P container);

(2) Stating that the donor-eligibility determination has not been completed; and

(3) Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except under the terms of paragraph (d) of this section.

(d) Use in cases of urgent medical need.

(1) This subpart C does not prohibit the implantation, transplantation, infusion, or transfer of an HCT/P from a donor for whom the donor-eligibility determination is not complete if there is a documented urgent medical need for the HCT/P, as defined in §1271.3(u).

(2) If you make an HCT/P available for use under the provisions of paragraph (d)(1) of this section, you must prominently label it “NOT EVALUATED FOR INFECTIOUS SUBSTANCES,” and “WARNING: Advise patient of communicable disease...”
risks.” The following information must accompany the HCT/P:

(i) The results of any donor screening required under §1271.75 that has been completed;

(ii) The results of any testing required under §1271.80 or 1271.85 that has been completed; and

(iii) A list of any screening or testing required under §1271.75, 1271.80 or 1271.85 that has not yet been completed.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (d)(1) of this section, you must document that you notified the physician using the HCT/P that the testing and screening were not complete.

(4) In the case of an HCT/P used for an urgent medical need under the provisions of paragraph (d)(1) of this section, you must document that you notified the physician using the HCT/P of the results of testing and screening.

§ 1271.75 How do I screen a donor?

(a) All donors. Except as provided under §1271.90, if you are the establishment that performs donor screening, you must screen the donor of cells or tissue by reviewing the donor’s relevant medical records for:

(1) Risk factors for, and clinical evidence of, relevant communicable disease agents and diseases, including:

(i) Human immunodeficiency virus; (ii) Hepatitis B virus; (iii) Hepatitis C virus;

(iv) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease;

(v) Treponema pallidum; and

(2) Communicable disease risks associated with xenotransplantation.

(b) Donors of viable, leukocyte-rich cells or tissue. In addition to the relevant communicable disease agents and diseases for which screening is required under paragraph (a) of this section, and except as provided under §1271.90, you must screen the donor of viable, leukocyte-rich cells or tissue by reviewing