

listed, the identity by established name and proprietary name, and the date of discontinuance. We request but do not require that you include the reason for discontinuance with this information.

(3) A list of each HCT/P for which a notice of discontinuance was submitted under paragraph (c)(2) of this section and for which you have resumed recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including the identity by established name and proprietary name, the date of resumption, and any other information required by § 1271.25(b) not previously submitted.

(4) Any material change in any information previously submitted. Material changes include any change in information submitted on Form FDA 3356, such as whether the HCT/P meets the criteria set out in § 1271.10.

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, you must submit an amendment to registration within 5 days of the change.

§ 1271.27 Will FDA assign me a registration number?

(a) FDA will assign each location a permanent registration number.

(b) FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) A copy of the Form FDA 3356 filed by each establishment will be available for public inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for

firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

- (1) A list of all HCT/P's;
- (2) A list of all HCT/P's manufactured by each establishment;
- (3) A list of all HCT/P's discontinued; and
- (4) All data or information that has already become a matter of public record.

(b) You should direct your requests for information regarding HCT/P establishment registrations and HCT/P listings to the Office of Communication, Training and Manufacturers Assistance (HFM-48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

Subpart C—Donor Eligibility

SOURCE: 69 FR 29830, May 25, 2004, unless otherwise noted.

§ 1271.45 What requirements does this subpart contain?

(a) *General.* This subpart sets out requirements for determining donor eligibility, including donor screening and testing. The requirements contained in this subpart are a component of current good tissue practice (CGTP) requirements. Other CGTP requirements are set out in subpart D of this part.

(b) *Donor-eligibility determination required.* A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under § 1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor.

(c) *Prohibition on use.* An HCT/P must not be implanted, transplanted, infused, or transferred until the donor