be taken in response to the HCT/P deviation (e.g., recalls).

(3) You must report each such HCT/P deviation that relates to a core CGTP requirement on Form FDA–3486 available at *http://www.fda.gov/cber/biodev/bpdrform.pdf*, within 45 days of the discovery of the event either electronically at *http://www.fda.gov/cber/biodev/biodevsub.htm* or by mail to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (HFM–600), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

§ 1271.370 Labeling.

The following requirements apply in addition to §§ 1271.55, 1271.60, 1271.65, and 1271.90:

(a) You must label each HCT/P made available for distribution clearly and accurately.

(b) The following information must appear on the HCT/P label:

(1) Distinct identification code affixed to the HCT/P container, and assigned in accordance with § 1271.290(c);

(2) Description of the type of HCT/P;

(3) Expiration date, if any; and

(4) Warnings required under § 1271.60(d)(2), § 1271.65(b)(2), or § 1271.90(b), if applicable and physically possible. If it is not physically possible to include these warnings on the label, the warnings must, instead, accompany the HCT/P.

(c) The following information must either appear on the HCT/P label or accompany the HCT/P:

(1) Name and address of the establishment that determines that the HCT/P meets release criteria and makes the HCT/P available for distribution;

(2) Storage temperature;

(3) Other warnings, where appropriate; and

(4) Instructions for use when related to the prevention of the introduction, transmission, or spread of communicable diseases.

[69 FR 68686, Nov. 24, 2004, as amended at 70 FR 29952, May 25, 2005]

Subpart F—Inspection and Enforcement of Establishments Described in § 1271.10

SOURCE: 69 FR 68687, Nov. 24, 2004, unless otherwise noted.

§ 1271.390 Applicability.

The provisions set forth in this subpart are applicable only to HCT/Ps described in § 1271.10 and regulated solely under section 361 of the Public Health Service Act and the regulations in this part, and to the establishments that manufacture those HCT/Ps. HCT/Ps that are drugs or devices regulated under the act, or are biological products regulated under section 351 of the Public Health Service Act, are not subject to the regulations set forth in this subpart.

§ 1271.400 Inspections.

(a) If you are an establishment that manufactures HCT/Ps described in § 1271.10, whether or not under contract, you must permit the Food and Drug Administration (FDA) to inspect any manufacturing location at any reasonable time and in a reasonable manner to determine compliance with applicable provisions of this part. The inspection will be conducted as necessary in the judgment of the FDA and may include your establishment, facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers, and controls required to be maintained under the part. The inspection may be made with or without prior notification and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) FDA will call upon the most responsible person available at the time of the inspection of the establishment and may question the personnel of the establishment as necessary to determine compliance with the provisions of this part.

(d) FDA's representatives may take samples, may review and copy any records required to be kept under this part, and may use other appropriate