Food and Drug Administration, HHS

§ 1270.42 Human tissue offered for import.

(a) When human tissue is offered for entry, the importer of record must notify the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which the tissue is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part.

(b) Human tissue offered for import must be quarantined until the human tissue is released by FDA.

§ 1270.35 Specific records.

Records shall be maintained that include, but are not limited to:

(a) Documentation of all required infectious disease tests;

(b) Information on the identity and relevant medical records of the donor, as required by §1270.21(e) in English or, if in another language translated to English and accompanied by a statement of authenticity by the translator which specifically identifies the translated document;

(c) Documentation of the receipt and/or distribution of human tissue; and

(d) Documentation of the destruction or other disposition of human tissue.

Subpart D—Inspection of Tissue Establishments

§ 1270.41 Inspections.

(a) An establishment covered by these regulations in this part, including any location performing contract services, shall permit an authorized inspector of the Food and Drug Administration (FDA) to make at any reasonable time and in a reasonable manner such inspection of the establishment, its facilities, equipment, processes, products, and records as may be necessary to determine compliance with the provisions of this part. Such inspections may be made with or without notice and will ordinarily be made during regular business hours.

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

(c) The inspector shall call upon a responsible person of the establishment and may question the personnel of the establishment as the inspector deems necessary.

(d) The inspector may review and copy any records required to be kept pursuant to part 1270.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of human tissue will be handled in accordance with FDA’s procedures on disclosure of information as set forth in 21 CFR part 20 of this chapter.

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