§ 1270.43 Retention, recall, and destruction of human tissue.

(a) Upon a finding that human tissue may be in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may:

1. Serve upon the person who distributed the tissue a written order that the tissue be recalled and/or destroyed, as appropriate, and upon persons in possession of the tissue that the tissue shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the tissue is confirmed; and/or

2. Take possession of and/or destroy the violative tissue.

(b) The written order will ordinarily provide that the human tissue be recalled and/or destroyed within 5 working days from the date of receipt of the order and will state with particularity the facts that justify the order.

(c) After receipt of an order under this part, the person in possession of the human tissue shall not distribute or dispose of the tissue in any manner except to recall and/or destroy the tissue consistent with the provisions of the order, under the supervision of an authorized official of FDA.

(d) In lieu of paragraphs (b) and (c) of this section, other arrangements for assuring the proper disposition of the tissue may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include providing FDA with records or other written information that adequately assure that the tissue has been recovered, screened, tested, processed, stored, and distributed in conformance with part 1270.

(e) Within 5 working days of receipt of a written order for retention, recall, and/or destruction of tissue (or within 5 working days of the agency’s possession of such tissue), the recipient of the written order or prior possessor of such tissue shall request a hearing on the matter in accordance with part 16 of this chapter. The order for destruction will be held in abeyance pending resolution of the hearing request.

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Subpart A—General Provisions

Sec. 1271.1 What are the purpose and scope of this part?
1271.3 How does FDA define important terms in this part?
1271.10 Are my HCT/P’s regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
1271.15 Are there any exceptions from the requirements of this part?
1271.20 If my HCT/P’s do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?

Subpart B—Procedures for Registration and Listing

1271.21 When do I register, submit an HCT/P list, and submit updates?
1271.22 How and where do I register and submit an HCT/P list?
1271.25 What information is required for establishment registration and HCT/P listing?
1271.26 When must I amend my establishment registration?
1271.27 Will FDA assign me a registration number?
1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

Subpart C—Donor Eligibility

1271.45 What requirements does this subpart contain?
1271.47 What procedures must I establish and maintain?
1271.50 How do I determine whether a donor is eligible?
1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I maintain?
1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?
1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?
1271.75 How do I screen a donor?
1271.80 What are the general requirements for donor testing?
1271.85 What donor testing is required for different types of cells and tissues?