

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
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23 December 1993
Special Distribution

(93-2265)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1.	Party to Agreement notifying: <u>UNITED STATES</u>
2.	Agency responsible: Food and Drug Administration (443)
3.	Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Human tissue
5.	Title and number of pages of the notified document: Human Tissue Intended for Transplantation (8 pages)
6.	Description of content: The Administration is issuing an interim rule to require certain infectious disease testing, donor screening, and record-keeping to help prevent the transmission of Aids and Hepatitis through human tissue used in transplantation. The regulations are effective upon publication. The new regulations require all facilities engaged in procurement, processing storage, or distribution of human tissues intended for transplant to ensure that minimum required infectious disease testing has been performed and that records documenting such testing for each tissue are available for inspection. The regulations also provide authority for the agency to conduct inspections of such facilities and to detain, recall, or destroy tissue for which appropriate documentation is not available.
7.	Objective and rationale: Health; this action is in response to growing concerns that some human tissue products are being offered for transplantation use without even the minimum donor testing and screening needed to protect recipients against Human Immunodeficiency Virus infection and Hepatitis infection.
8.	Relevant documents: 58 FR 65514, 16 December 1993; 21 CFR Parts 16 and 1270.
9.	Proposed date of adoption and entry into force: The interim rule is effective 14 December 1993.
10.	Final date for comments: 14 March 1994
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: