

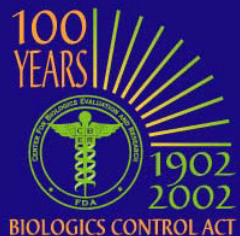
Donor Issues Scenario Based Panel “FDA Introduction”

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Overview

- Introduction
- Overview of regulations and guidance
- Resources
- Contact information

Legal Authority

- Public Health Service Act
 - Section 361—The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Overview of US Tissue-related regulations currently in place

Regulation Subparts	Proposed	Final	Effective Date
Establishment Registration and Product Listing	1998	2001	2001 for establishments regulated under 1270; 2004 for newly regulated establishments
Donor Eligibility	1999	2004	May 25, 2005
Current Good Tissue Practices (GTP): Inspection and Enforcement	2001	2004	May 25, 2005

Guidance

- Draft – Preventive Measures to Reduce the Possible Risk of Transmission of CJD/vCJD by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - June 2002
- Draft – Eligibility Determination for Donors of HCT/Ps - May 2004
- Final - donor eligibility guidance will combine the above drafts – FDA is addressing comments to the docket
- Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements – September 2006

Guidance

- MedWatch Form 3500A: Mandatory Reporting of Adverse Reactions Related to HCT/Ps – November 2005
- Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of HCT/Ps – November 2004
- Current Good Tissue Practices guidance – currently leveraging with industry professional associations to develop draft guidance
- <http://www.fda.gov/cber/tissue/docs.htm>

Donor Testing Information

- Donor Screening Tests for HCT/P Donors
<http://www.fda.gov/cber/tissue/prod.htm>
- Additional information on other donor screening tests with indications for use in living donors can be found at
<http://www.fda.gov/cber/products/testkits.htm>

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