PROPOSED NEW REGULATORY FRAMEWORK FOR HUMAN TISSUE

CONCERN 1: DISEASE TRANSMISSION

(Does the Tissue Pose a Risk of Transmitting Diseases Such as AIDS or Hepatitis?)

Product Characteristic	Industry Action Required	Submission to FDA
Tissue transplanted within one person during a single surgical procedure	None	None
Tissue transplanted within one person that has been banked, processed, or shipped	Disease screening and testing recommended; Good Tissue Practices (GTPs) (handling, recordkeeping, and labeling procedures) would be required	None
Tissue donated from one person to another	Subject to GTPs; disease screening and testing would be required	None

CONCERN 2: CONTROL OF PROCESSING
(What Kinds of Handling and Processing Controls Would Be Necessary?)

Product Characteristic	Industry Action Required	Submission to FDA
Tissue transplanted within one person during a single surgical procedure	None	None
Minimally processed structural[3] tissue used for its normal function and having no nontissue parts; or reproductive tissue[4] used for its normal function, and having no non-tissue parts	Would be subject to GTPs relating to contamination, integrity, and function	None
Minimally processed metabolic tissue[5] transplanted into the same person, or into a family member, used for its normal function, and having no nontissue parts	Would be subject to GTPs relating to contamination, integrity, and function	None
Metabolic tissue transplanted to another person not related to the donor; or that has been manipulated, or is used for other than its normal function, or has nontissue parts	Would have more comprehensive processing controls than GTPs (to address clinical safety/effectiveness concerns)	Human testing exemptions and marketing approval by FDA would be required. (In certain cases, certification to standards may substitute for data submission.)
Structural tissue that has been manipulated, or is used for other than its normal function, or has nontissue parts	Would have more comprehensive processing controls than GTPs (to address clinical safety and effectiveness concerns)	Human testing exemptions and marketing approval by FDA would be required.

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[3] Structural tissue comprises such tissue as corneas, ligaments, bones, cartilage, tendons, dura mater, and heart valves.

[4] Reproductive tissue comprises such tissue as ova, semen, and embryos.

[5] Metabolic tissue is tissue that affects the function of the entire body (e.g., umbilical cord stem cells infused into a patient to reconstitute the cellular elements of the patient's blood, or pancreatic islet cells implanted to treat diabetes).

CONCERN 3: CLINICAL SAFETY
(Does the Product Need FDA Approval for Safety/Effectiveness?)

Product Characteristic	Industry Action Required	Submission to FDA
Minimally processed structural tissue used for its normal function, and without nontissue parts; or metabolic tissue that is used in the same person or in a close relative of the donor that is minimally processed, used for its normal function, and has no nontissue parts.	None	None
Tissue used for structural reconstruction or repair that: 1) has been manipulated; or 2) is used for other than its normal function; or 3) is combined with nontissue parts	Would have to gather clinical safety and effectiveness data	Human testing exemptions and marketing approval required; standard for effectiveness determination would be consistent with that for comparable devices
Metabolic tissue used in a person not related to the donor, or that: 1) has been manipulated; or 2) is used for other than its normal function; or 3) is combined with nontissue parts	Would have to gather clinical safety and effectiveness data	Human testing exemptions and marketing approval by FDA required; standard for effectiveness determination would be consistent with that for biologics
Reproductive tissue that is: 1) manipulated; 2) used for other than its normal function; or 3)combined with nontissue parts	Would have to gather clinical safety and effectiveness data	Human testing exemptions and marketing approval by FDA required; standard for effectiveness determination would be consistent with that for biologics.

CONCERN 4: CLAIMS MADE BY MANUFACTURERS
(What Regulation Is Needed of Product Labeling and Advertising?)

Product Characteristic	Industry Action Required	Submission to FDA
Tissue transplanted within one person during a single surgical procedure	None	None
All other tissue	Clear, accurate, balanced, and nonmisleading labeling and promotion	No FDA submission concerning labeling for products regulated only under section 361; for products regulated under section 351 and/or FDC Act, normal rules would apply

CONCERN 5: BASELINE KNOWLEDGE OF INDUSTRY
(Should Tissue Products Be Registered with FDA?)

Product Characteristic	Industry Action Required	Submission to FDA
Tissue transplanted within one person during a single surgical procedure	None	None
All other tissue	Notification of FDA	Registration and listing under new regulation under 361 or under section 510 of the FDC Act