Petition to Reclassify Allogeneic Pancreatic Islet Cells as Human Organs Under the National Organ Transplant Act, and to Transfer Regulatory Oversight from FDA Biologics Licensing to the HRSA/OPTN Organ Transplant Framework

To the Division of Dockets Management, U.S. Food and Drug Administration, U.S. Department of Health and Human Services:

I am submitting this comment in Docket No. FDA-2026-P-7930 to formally register my objection to the continued classification of allogeneic pancreatic islet cells — the insulin-producing micro-organs of the pancreas — as a Section 351 biologic drug under the Public Health Service Act, and to state my support for the Petitioner's request that oversight of islet transplantation be transferred to the organ transplantation framework administered by the Health Resources and Services Administration (HRSA), the Organ Procurement and Transplantation Network (OPTN), and the United Network for Organ Sharing (UNOS). I write as a concerned citizen with a direct stake in the outcome of this proceeding, and I submit the following statutory, regulatory, and scientific grounds in support of the requested reclassification.

I. The Current Classification Is Legally Untenable Under the Plain Text of the National Organ Transplant Act

Congress amended the National Organ Transplant Act (NOTA) in 1988 to define “human organ” to expressly include the pancreas “or any subpart thereof” (42 U.S.C. § 274e(c)(1), as amended by Pub. L. 100-607). Islets of Langerhans are, as a matter of anatomical and physiological fact, a subpart of the pancreas: they are clusters of living, vascularized, multi-cell-type micro-organs — composed of alpha, beta, delta, and PP cells arranged in organized architecture — that perform an organ-level endocrine function by regulating blood glucose through coordinated insulin and glucagon secretion (CellR4, 2021). They are not a purified molecule, a synthesized compound, or an immortalized cell line subject to the drug and biologic framework Congress built for Section 351 of the Public Health Service Act. Where a statute's plain text already covers the article at issue, an agency's contrary administrative practice does not override that text; it is the text, not the agency's convenience, that controls. FDA's own Center for Biologics Evaluation and Research approved Lantidra (donislecel-jujn) in 2023 as the first allogeneic pancreatic islet cell therapy for type 1 diabetes under a Biologics License Application pursuant to Section 351 of the Public Health Service Act (FDA Summary Basis for Regulatory Action; FDA press announcement) — a classification decision made administratively, without formal rulemaking to reconcile it with NOTA's 1988 statutory amendment or to update the OPTN Final Rule's definition of “human organ” (42 C.F.R. Part 121) to expressly address islets.

II. FDA's Own Regulatory Framework Treats Biologically Identical Tissue Inconsistently

The internal inconsistency of the current rule is itself evidence that the classification is arbitrary rather than scientifically grounded. Islets isolated from a patient's own pancreas and returned to that same patient (autologous transplantation), and islets recovered from a living related donor, are not regulated as drugs and require no Biologics License Application. Only islets recovered from a deceased, unrelated donor — processed by the identical isolation and purification techniques — are swept into Section 351 drug regulation (Islets for US Collaborative position statement, regulations.gov). The cells themselves are biologically indistinguishable across these categories; only the source of procurement differs, which is precisely the distinction NOTA and the OPTN framework already exist to regulate for every other transplantable organ, including the whole pancreas.

III. Islets Fail the Practical and Scientific Hallmarks of a Drug and Satisfy the Hallmarks of a Transplantable Organ

The clinical and scientific record establishes that islets function as organ tissue, not as a drug product, on every relevant measure. They cannot be frozen, stockpiled, or stored on a shelf; they must be transplanted within hours of procurement, exactly as a kidney, liver, or heart must be (Molecular Therapy, 2023; Frontiers in Endocrinology, 2022). They retain their own internal microvasculature and integrate directly with the recipient's blood supply following transplantation. Recipients require the same category of immunosuppressive regimens used for solid-organ transplant recipients generally, not a drug-dosing regimen calibrated to a pharmacologic agent. Moreover, the “minimal manipulation” standard FDA applied to trigger Section 351 drug regulation — treating routine, clinically necessary cold preservation of islets during the 72-hour window between procurement and transplantation as disqualifying “cell culture” — has been directly challenged by clinical data showing no biologically relevant alteration of islet structure or function during that interval (American Society of Transplantation Board of Directors letter to FDA). More than fifty transplant physicians and researchers, organized as the Islets for US Collaborative and including Dr. Piotr Witkowski of the University of Chicago, have formally petitioned FDA on this exact basis, and FDA's own Cellular, Tissue, and Gene Therapies Advisory Committee voted 12–4 to endorse the Lantidra Biologics License Application only after acknowledging this unresolved classification dispute on the record (Medscape, 2021; Journal of Clinical Medicine, 2021).

IV. Reclassification Would Not Eliminate Oversight — It Would Correct Which Framework Applies

Nothing in this comment asks the agencies to abandon regulatory oversight of islet safety. HRSA, OPTN, and UNOS already manage procurement, allocation, donor screening, and safety oversight for every other transplantable organ in the country, including the whole pancreas, under a framework Congress and HHS specifically built for time-sensitive, non-storable human organ tissue. FDA would retain authority over islet processing under Good Tissue Practice standards, exactly as it already does for other minimally manipulated human cell and tissue products exempt from Biologics License Application requirements under Section 361 of the Public Health Service Act (Frontiers in Endocrinology, 2022). What changes is not whether islets are regulated, but which of two existing, congressionally authorized frameworks governs them — and the framework NOTA's text already describes is the organ transplantation framework, not the drug licensure pathway.

V. This Misclassification Imposes an Ongoing and Measurable Human Cost

Type 1 diabetes affects an estimated 1.8 million Americans, who face a lifetime of insulin dependence, hypoglycemic risk, and progressive vascular and neurological complications. Islet transplantation has already demonstrated the ability to restore insulin independence and eliminate life-threatening hypoglycemic unawareness in appropriately selected patients, and has functioned as standard of care — regulated as an organ or tissue transplant rather than a licensed drug — in Canada, the European Union, Australia, and Japan for more than two decades (Molecular Therapy, 2023; Frontiers in Endocrinology, 2022). In the United States, the Biologics License Application pathway has confined access to a narrow, FDA-licensed commercial product and a small number of clinical trial sites, even as thousands of islet transplant procedures have been safely performed worldwide under organ-transplant regulation (Diabetes Therapy, 2025). Every year this misclassification persists is a year in which a scientifically validated, already-approved path toward a functional cure for type 1 diabetes is delayed by a regulatory label rather than by clinical evidence. This proceeding, and the underlying petition it addresses, has also drawn the attention of Breakthrough T1D's March 2026 proposal to HHS, the Islets for US Collaborative's joint reclassification proposal, and bipartisan letters from the Senate and House Diabetes Caucuses, together with the pending Islet Cell Transplant Coverage and Long-Term Care Savings Act (ISLET Act, S. 3105 / H.R. 8018) — all of which reflect a growing legislative and clinical consensus that the current classification is scientifically indefensible and administratively overdue for correction.

VI. Requested Action

For the foregoing reasons, I respectfully urge FDA and HHS to grant the pending petition in Docket No. FDA-2026-P-7930 and to:

1. Initiate rulemaking to amend the OPTN Final Rule's definition of “human organ” (42 C.F.R. Part 121) to expressly include pancreatic islet cells as a subpart of the pancreas, consistent with the existing statutory definition at 42 U.S.C. § 274e(c)(1);

2. Reclassify allogeneic pancreatic islet cell products from Section 351 biologic regulation to the organ transplantation framework overseen by HRSA, OPTN, and UNOS, while preserving FDA's Good Tissue Practice oversight of islet processing and safety under Section 361 of the Public Health Service Act;

3. Eliminate the Biologics License Application requirement for allogeneic islet transplantation, consistent with the exemption already granted to autologous and living-related-donor allogeneic islet transplantation; and

4. Publish a public timeline for this reclassification proceeding, including formal reconsideration of the positions raised by the Islets for US Collaborative and the Cellular, Tissue, and Gene Therapies Advisory Committee, and confirmation of this comment's inclusion in the administrative record for Docket No. FDA-2026-P-7930.

I ask that this comment, and the scientific and statutory record cited herein, be entered into the public docket and considered as part of the agency's evaluation of the pending petition.

Respectfully submitted,

Concerned Citizen

HOW TO SUBMIT THIS COMMENT (delete before printing/distributing as a final copy)

1. Go to regulations.gov and search Docket No. FDA-2026-P-7930, or open it directly at regulations.gov/docket/FDA-2026-P-7930.

2. Click “Comment” on the docket page. Paste the letter text above into the comment box, or attach this PDF as a supporting file.

3. Regulations.gov requires a name and contact email to submit, separate from the letter's signature block — the letter itself is signed generically as “Concerned Citizen” and contains no personal identifying information, but the submission form will ask for basic contact details as required by the portal.

4. Personalizing the letter with a first-person connection to type 1 diabetes (yours, a family member's, or a patient's) strengthens the record, but is optional — the letter stands on its own as written.