US FDA Guidance and Reference Documents for Cell and Gene Therapy and Regenerative Medicine	Release Date
Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry	January 2020
Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry	January 2020
Long Term Follow-up After Administration of Human Gene Therapy Products; Draft Guidance for Industry	January 2020
Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry	January 2020
Human Gene Therapy for Hemophilia; Draft Guidance for Industry	January 2020
Human Gene Therapy for Rare Diseases; Draft Guidance for Industry	January 2020
Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry	January 2020
Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry	February 2019
Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry	February 2019
Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff	December 2017
Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry	November 2017
Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271; Guidance for Industry	September 2017
Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271	March 2016
Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Guidance for Industry	June 2015
Guidance for Industry: BLA for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System	March 2014
IND Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System - Guidance for Industry and FDA Staff	March 2014
Guidance for Industry: Preclinical Assessment of Investigational Cellular and Gene Therapy Products	November 2013
Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage	December 2011
Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)	December 2011

Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products	January 2011
Guidance for Industry: Cellular Therapy for Cardiac Disease	October 2010
Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)	April 2008
Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs)	April 2008
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry	August 2007
Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide	August 2007
Compliance with 21 CFR Part 1271.150(c)(1) – Manufacturing Arrangements	September 2006
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998