Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2021

(Updated June 2021)

This is the list of guidance topics CBER is considering for development during Calendar Year 2021. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CBER has already issued Level 1 draft guidances that may be finalized following review of public comments. We currently intend to develop guidance documents on these topics; however, the Center is neither bound by this list of topics, nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list.

For further information regarding specific topics or guidances, please contact the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010, ocod@fda.hhs.gov.

Guidance Documents CBER is Planning to Issue in 2021:

CATEGORY – Blood and Blood Components:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry
- Collection of Platelets by Automated Methods; Guidance for Industry[1]
- Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Issued January 2021 and updated February 2021)
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry (We are no longer pursuing this guidance. We issued an informational document regarding the risk of Zika virus transmission by blood and blood components and withdrew the July 2018 guidance in May 2021)
- Compliance Policy Regarding Donation Suitability Requirements; Draft Guidance for Industry

[1] We intend to issue a Level 2 guidance to revise existing recommendations to address statistical sampling plans for process validation.

CATEGORY – Tissues and Advanced Therapies:

- Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Guidance for Industry

- Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry (Issued January 2021)

- Considerations for the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry

- Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Therapies; Draft Guidance for Industry

- Studying Multiple Versions of a Cellular or Gene Therapy Product in a Clinical Trial; Draft Guidance for Industry

- Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide; Guidance for Industry

- Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency; Guidance for Industry (Issued January 2021)

CATEGORY – Vaccines

- Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry (Updated May 2021)

CATEGORY – Other

- Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Guidance for Industry