Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2022

(January 2022)

This is the list of guidance topics CBER is considering for development during Calendar Year 2022. 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 2022:

CATEGORY – Blood and Blood Components:

- Blood Pressure and Pulse Donor Eligibility Requirements; Compliance Policy; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry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 (Updated January 2022)
- Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Draft Guidance for Industry
- An Acceptable Circular of Information for the Use of Human Blood and Blood Components: 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:

- Human Gene Therapy for Neurodegenerative Diseases; Guidance for Industry
- Considerations for the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry
- Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Therapies; Draft Guidance for Industry
- Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide; Guidance for Industry
- Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Draft Guidance for Industry and Staff
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry

CATEGORY – Vaccines:

- Emergency Use Authorization for Vaccines to Prevent COVID-19; Draft Guidance for Industry and Staff