The Focal Point: Advocacy & Legislative Update
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FDA Releases Annual Report on Biological Product and HCT/P Deviations

The U.S. Food and Drug Administration's (FDA) Center for Biologics Research and Evaluation (CBER) on Wednesday released its annual summary of deviations reported by biologics, blood and blood component, and human cells, tissues, and cellular and tissue-based products (HCT/P) manufacturers.

During FY2017, CBER says it received 52,231 deviation reports, a 1.9% increase from FY2016. Tissue HCT/P manufacturers reported 96 deviations in FY17, 29 fewer reports than in the previous year, with five fewer reporting establishments. The report also goes into detail on the most commonly reported HCT/P Deviation Codes for 361 HCT/P establishments.

HCT/P Deviation Code	Cellular HCT/P	Tissue HCT/P	TOTAL
Receipt, Pre-Distribution, Shipment & Distribution	86	31	117 (52.9%)
Processing and Processing Controls	26	3	29 (13.1%)
Donor Eligibility	1	28	29 (13.1%)
Donor Testing	3	12	15 (6.8%)
Supplies and Reagents	8	4	12 (5.4%)
Donor Screening	0	11	11 (5.0%)
Labeling Controls	0	3	3 (1.4%)
Recovery	0	3	3 (1.4%)
Environmental Control	1	0	1 (0.5%)
Storage	0	1	1 (0.5%)
Equipment	0	0	0 (0.0%)
Total	**125**	**96**	**221 (100%)**

FDA Approves Procleix Zika Virus Assay

The FDA approved the Biologics License Application (BLA) for the Procleix Zika Virus Assay by Grifols Diagnostic Solutions, Inc. This assay is a qualitative in vitro nucleic acid test for the detection of Zika Virus (ZIKV) RNA in plasma specimens from individual human donors, including volunteer donors of whole blood and blood components for transfusion. It is also intended for use in testing plasma or serum specimens to screen living donors of organs and tissues, and in testing blood specimens to screen cadaveric (non-heart beating) donors. This assay is not intended for use as an aid in the diagnosis of Zika virus infection.

FDA Releases Revised Final Guidance on Zika Testing for Blood Establishments

The FDA published revised recommendations for Zika testing of blood and blood components provided to blood banks, shortly after licensing the Procleix Zika virus (ZIKV) blood donor screening assay.

The final guidance, "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components," is for immediate implementation. Blood establishments must continue to test all donated Whole Blood and blood components for Zika virus using a nucleic acid test. But they added that pooled donation using an FDA-licensed screening test may be sufficient, unless there is a higher risk of local mosquito-borne

transmission of the virus in a specific geographic area, which would trigger the need for individual donation testing.

As an alternative to testing, blood establishments may use FDA-approved pathogen reduction technology for indicated blood components (i.e. platelets and plasma) to reduce the risk of ZIKV transmission.

FDA does not recommend pre-donation assessment for ZIKV risk factors for donors of blood and blood components such as possible exposure to ZIKV through travel or sexual contact, because appropriate testing strategies are available. The agency continues to recommend pre-donation assessment for donors of human cells, tissues, or cellular or tissue-based products (HCT/Ps).

FDA Updates Key Staff Directory

The FDA updated the CBER Key Staff Directory last week, with titles and phone numbers for key staff in CBER offices and divisions.

CBER Releases Science Symposium Videos

The FDA released the videos from their two-day public symposium entitled "2018 Center for Biologics Evaluation and Research Science Symposium." The purpose of the public symposium was to discuss scientific topics related to the regulation of biologics and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision making and to provide a forum for developing collaborations within FDA and with external organizations.

eSubmitter Download and Installation

The FDA updated their eSubmitter software and Download Quick Guide. The eSubmitter software is used for the electronic submission of regulatory information to FDA.

At this time, eSubmitter may be used to submit the following to their various agencies:

CDER: GDUFA submissions
CDRH: Medical Device ISO 13485, Radiological Health Reports and Correspondence, OIVD 510(k)s, eCopies, and the MedWatch 3500A form for medical device adverse event reports
CBER: Biologics Licensing Applications, and ICSR Adverse Event Reporting