The Focal Point: Advocacy & Legislative Update
October 8, 2019

EBAA Submits Comments to HHS Regarding Proposed Revisions to PHS Guidelines

The EBAA submitted comments on behalf of our 75 U.S. member eye bank organizations to the U.S. Department of Health and Human Services proposed revisions to the ***2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Transmission through Organ Transplantation.***

We applauded their efforts to promote organ utilization and transplantation while balancing and mitigating the risk of disease transmission from organ donors. EBAA supports the majority of the proposed revisions, particularly the elimination of "Increased Risk Donor (IRD)" designation, the simplification of the criteria and shortening the timeframe for medical/social risk evaluation to 30 days.

EBAA is however concerned with, and strongly opposes, the proposed requirement of additional nucleic acid testing (NAT) on donor specimen collected within 24 hours prior to organ recovery. The results of the additional NAT testing would not be available until after transplant, thus not preventing disease transmission at all. The additional time, logistics and costs are not warranted. Repeat NAT testing would increase the likelihood of false positive results, which would then make the donor ineligible to donate tissues.

To read the comments submitted by EBAA, please click here.

FDA Updates Deviation Reporting Codes for FY2020

FDA recently revised the deviation codes utilized in Biological Product Deviation (BPD) and HCT/P Deviation Reporting. Although there were no changes to the HCT/P Deviation Codes for FY2020, eye banks should review the attached list to assign a specific code to a reportable event submitted to FDA.

Use the guidance document, "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" to determine if you must report an event. A deviation is only required to be reported if it relates to core Current Good Tissue Practices (CGTP) [see 21 CFR 1271.150(b)], involves a distributed HCT/P, and occurs

in your facility or a facility that performs a manufacturing step for you under contract, agreement, or other arrangement [see 21 CFR 1271.350(b)(2)].

The following list is a summary of abbreviations used to identify each category of HCT/P Deviation Codes based on applicable core CGTP:

- DE - Donor Eligibility
- DS - Donor Screening
- DT - Donor Testing
- FA - Facilities
- EC - Environmental Control
- EQ - Equipment
- SR - Supplies and Reagents
- RE - Recovery
- PC - Processing and Processing Controls
- LC - Labeling Controls
- ST - Storage
- SD - Receipt, Pre-Distribution, Shipment, and Distribution

CBER FY 2019 Recall Postings

The U.S. Food and Drug Administration (FDA) released the number of recalls for fiscal year 2019. Of the 16 tissue recalls for the year, there were 1 Class I, 13 Class II, and 2 Mixed Class I/II recalls.

Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

FDA Announces Final Reorganization of the Office of New Drugs

FDA announced the reorganization of the Office of New Drugs (OND), which is part of the Center for Drug Evaluation and Research (CDER). The reorganization will group OND offices and divisions by therapeutic area to distribute workload and align divisions with clearer and more focused areas of expertise. FDA is increasing the number of offices that oversee review divisions covering different therapeutic areas, from six to eight, and increasing the clinical divisions from the current 19 to 27 plus six non-clinical review divisions.

The Division of Ophthalmology (DO) will now be under the Office of Specialty Medicine (OSM), which also contains the Division of Medical Imaging and Radiation Medicine.

FDA Compiles List of NDAs Transitioning to BLAs Next March

The Biologics Price Competition and Innovation Act of 2009 will trigger the conversion of various new drug applications into biologics license applications on March 23, 2020, because of the amended definition of biological products to include a “protein (except any chemically synthesized polypeptide).” FDA released a preliminary list of the new drug applications (NDAs) that will be converted to biologics license applications (BLAs) in March.

According to draft guidance released last December, FDA interprets the term “protein” to mean “any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size.” And FDA said it interprets the term “chemically synthesized polypeptide” to mean any alpha amino acid polymer that “(1) is made entirely by chemical synthesis and (2) is greater than 40 amino acids, but less than 100 amino acids in size.”
The change effectively means that any follow-on products associated with the NDAs will require approval as biosimilars.

Preliminary List of Approved NDAs for Biological Products That Will Be Deemed to be BLAs on March 23, 2020 (current as of August 31, 2019

US Issues Travel Warning for Tanzania Over Probable Ebola Death

Officials from the United States updated warnings for travelers to Tanzania following the death of a doctor from probable Ebola virus disease in Dar es Salaam. This individual reportedly traveled around the country while ill, including to the cities of Songea, Njombe, and Mbeya.

The updates from the U.S. Centers for Disease Control and Prevention and U.S. Department of State followed a Sept. 21 statement from the World Health Organization asking the Tanzanian government for additional information about the death.

Travelers to Tanzania should avoid direct contact with people who are ill and monitor themselves for symptoms of Ebola both during and for 3 weeks after travel.

Descovy Approved as Second PrEP Drug for HIV

The FDA has approved a second drug for HIV-1 preexposure prophylaxis (PrEP) as part of ongoing efforts to end the HIV epidemic.

Gilead Sciences’ Descovy is a fixed-dose combination of emtricitabine (200 mg) and tenofovir alafenamide (25 mg). The approval indicates the drug can be used to prevent the disease in transgender women and HIV-negative men who have sex with men. Descovy is not indicated in individuals at risk for HIV-1 infection from receptive vaginal sex because the effectiveness in this population has not been evaluated.

New Biocompatible Corneal Inlays for Presbyopia

At the European Society of Cataract and Refractive Surgeons meeting, Pavel Stodulka, MD, PhD, speaks about two new concepts in corneal reshaping inlays for presbyopia that have overcome the biocompatibility problems of previous corneal implants. The first, by the biotech company Allotex, is made of corneal donor tissue. The second, by the Swedish company LinkoCare, is made of a bioengineered material similar to human tissue.

President Trump Issues an Executive Order on Medicare

President Donald Trump signed an executive order on October 3 - Protecting and Improving Medicare of Our Nation's Seniors – that directs HHS to propose regulations and implement administrative actions that encourage Medicare Advantage plans, in particular, to offer innovative plan designs and benefits including telehealth services and supplemental benefits not available in the traditional fee-for-service Medicare program.

Upcoming Events & Deadlines

October 10:	2019 EBAA Fall Leadership Meeting
October 10:	2019 Medical Advisory Board: Live Audio Broadcast
October 11:	2019 Cornea and Eye Banking Forum
October 13:	Run for Vision 5k (San Francisco)
October 14:	Slit Lamp Microscopy Seminar Registration Deadline
October 18:	Physician Leadership Program Nomination Deadline
November 6:	Webinar: Developing Ambassadors to Promote Your Mission
November 18:	2020 Annual Meeting: Presentation Proposal Deadline
February 18:	2020 Annual Meeting: Scientific Symposium Proposal Deadline