



# **EYE BANK ASSOCIATION of AMERICA**

## **THE FOCAL POINT** *Advocacy and Legislative Update* *February 3, 2015*

### **CBER Publishes List of Proposed Guidance Documents for CY 2015**

The Food and Drug Administration published a list of guidance topics that CBER is considering for development during Calendar Year 2015. This year's list includes two draft guidance documents of interest to eye banks, including:

- Draft Guidance for Industry: Homologous Use of Human Cells, Tissues, and Cellular and Tissue Based Products
- Draft Guidance for Industry: Manufacturer Investigation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Adverse Reactions

Additionally, FDA plans to publish several guidance documents for blood products that might eventually be considered for donors of HCT/Ps:

- Draft Guidance for Industry: Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus
- Draft Guidance for Industry: Revised Recommendations for Donor Deferral to Reduce the Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products
- Draft Guidance for Industry: Recommendations to Reduce the Risk of Transmission-transmitted Chikungunya Virus (CHIKV)

It is important to note that Syphilis and West Nile Virus, two topics on which we had expected guidances that could have adversely affected eye banking, is conspicuously absent from this list. EBAA has expressed our concerns about the impact that an excessively restrictive approach to these issues would have on donor suitability. We will continue to press these and related positions whenever we meet with our FDA partners.

Please note that CBER may develop guidance for topics not included on this list or refrain from developing a guidance for every topic listed.

## [Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2015](#)

### **FDA Releases Guidance on CGMP Requirements for Combination Products**

FDA released a draft guidance for industry entitled “[Current Good Manufacturing Practice Requirements for Combination Products](#).” The guidance provides background on combination products, including an overview of the final rule on CGMP requirements for combination products (78 FR 4307, January 22, 2013) (21 CFR part 4) and the role of the lead center and other Agency components with respect to combination product CGMP issues. The guidance addresses general considerations for CGMP requirements for combination products and the purpose and content of specific CGMP provisions addressed in part 4.

### **Joint Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee and Ophthalmic Devices Panel of the Medical Devices Advisory Committee**

The FDA announced a [joint meeting](#) of a public advisory committee of the Dermatologic and Ophthalmic Drugs Advisory Committee and Ophthalmic Devices Panel of the Medical Devices Advisory Committee on February 24, 2015 at the FDA White Oak Campus.

The committees will discuss new drug application (NDA) 203324, for riboflavin ophthalmic solutions with UV–A irradiation, submitted by Avedro, Inc. The combination products are used in corneal collagen cross-linking and proposed to be indicated for the treatment of progressive keratoconus or corneal ectasia following refractive surgery.