American Association of Tissue Banks®

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Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
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Olivia Ziolkowski, JD, MPH, Ombudsman
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Dear Mses. Mendoza and Ziolkowski,

The American Association of Tissue Banks (AATB) is aware of issues that accredited tissue establishments have been facing with regards to the Center for Biologics Evaluation and Research's (CBER) export program for CBER-regulated products, specifically the issuance of Certificate(s) to Foreign Government (CFG) for HCT/Ps.

We have received reports of increased scrutiny by CBER with an escalation of the verification process, including for those HCT/Ps that are solely regulated under PHS 361 and 21 CFR part 1271. Follow-up requests from CBER now include detailed documentation such as processing SOPs, intended use, and labeling, which were previously never required as part of the CFG request process. Such requests have been made for HCT/Ps that have already received documented Tissue Reference Group (TRG) recommendations, which were provided to CBER personnel reviewing the CFG request. The role of TRG letters and the criteria for CFG issuance seem to be evolving without notification to the industry. HCT/Ps that have received CFGs for many years without issue are now facing delays and additional scrutiny.

AATB-accredited establishments are reporting that, for the past 12-18 months, processing times have significantly increased, with some applications pending for over 6 months to a year. Previously, CFGs were issued within 1-3 weeks. Repeated attempts to contact pertinent CBER staff have gone unanswered. This lack of transparency and inconsistent feedback from CBER has led to confusion and establishments being unable to export HCT/Ps. Some applications have been canceled without clear justification.

AATB has reviewed the resources page "How to Enter a Certificate to Foreign Government (CFG) Application" available at https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/how-enter-certificate-foreign-government-cfg-application and we have found no information or guidance related to how and when additional requests for information are handled when CFG requests are submitted for products regulated solely under Section 361 of the PHS and 21 CFR Part 1271.

If there have been changes to the CFG application and issuance process, we would welcome a discussion with CBER OCBQ Division of Case Management so that we can inform AATB-accredited banks. We hope to help make the process more consistent, efficient, and transparent for both the HCT/P industry and CBER.

We are requesting your urgent attention to this matter in the form of a reply and would be happy to meet with pertinent staff at CBER OCBQ DCM as warranted.

I can be contacted at (703) 229-1042 and/or hanksk@aatb.org.

Best regards,

Kip J. Hanks, Director
Accreditation and Regulatory Affairs