Advancing Transfusion and Cellular Therapies Worldwide

America's Blood Centers® It's About Life.

American Red Cross

January 8, 2021

Peter Marks, M.D., Ph.D., Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Nicole Verdun, M.D., Director
Office of Blood Research and Review, CBER
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Drs. Marks and Verdun,

Since March of 2020, the U.S. blood community has been committed to the national effort to support the collection and distribution of COVID-19 convalescent plasma (CCP), in partnership with the Department of Health and Human Services, the U.S. Food and Drug Administration (FDA) and the Biomedical Advanced Research and Development Authority (BARDA). CCP serves as a bridge therapy providing a potentially life-saving treatment for critically ill patients until additional treatment options become available.

The implementation of the August 2020 Emergency Use Authorization (EUA) eased the administrative burden on hospitals and further expanded access to CCP, and blood centers are appreciative of the extended period of enforcement discretion granted in the revised EUA issued November 16, 2020.

The current EUA allows for testing to determine high/low titer levels by only two manufacturers. We are aware that multiple test manufacturers are submitting data which would enable FDA to evaluate additional testing platforms/assays for use under an amended EUA. While some blood centers have already implemented the currently approved tests, extension of the enforcement discretion period until evaluation and approval of other test candidates would allow for more flexibility and resiliency, particularly for laboratories desiring to perform this testing on existing (alternate) platforms. Implementing a new test on an existing platform is more efficient (in both cost and time) and lessens the burden for laboratories and blood centers already stretched thin. Substantial work is involved in implementing new testing, to negotiate contracts, implement changes and complete the extensive validation protocols necessary for critical systems protecting blood safety. In addition to changes in the laboratory (development of new workflows, standard operating procedures and staff training), considerable IT coding changes to blood establishment computer systems (BECS) are required. As a result of ICCBA's transition to "EA" products codes, IT coding changes are required for both the blood center BECS and hospital information systems to allow acceptance of CCP products using this new alphanumeric format. The need for this change to their computer systems is occurring as hospitals are dealing with the recent surges in COVID-19 cases and is placing an additional burden on them.

Therefore, we are requesting a further extension of the enforcement discretion period to ensure that CCP remains readily available to patients in need. An extension would provide the FDA additional time to review the feasibility of allowing alternate assays with robust performance characteristics and automation that provide blood centers additional options. Additional testing options will allow for more resiliency in the

system, as there will be alternate backup tests available if needed, and less demand on individual manufacturers to rapidly meet national demand for their platforms and reagents.

The nation's CCP program requires a more solid foundation by removing the time pressure to identify and implement less than optimal solutions by February 28, 2021, which is rapidly approaching. We recognize that there are a number of stakeholders involved in the collection, processing, distribution, and transfusion of CCP. Our organizations will continue to engage with all stakeholders in the blood community to ensure that additional perspectives or concerns are identified and brought forward.

Thank you very much for your ongoing support and partnership in the effort to bring CCP to patients in need. Should you have questions, please contact Sharon Carayiannis (571-340-4565, SCarayiannis@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Scott Webber (404-427-1414, scott.webber@redcross.org).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross