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American Red Cross

November 2, 2020

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). This serves as a bridge therapy providing a potentially life-saving treatment for critically ill patients until additional treatment options become available. The August 2020 Emergency Use Authorization (EUA) for CCP eased the administrative burden on hospitals to further expand access to patients in need. We appreciate the urgency around implementation of the EUA. In support of that effort and to ensure continued patient access to treatment with CCP, we are requesting additional time for effective transition to the new EUA requirements. Specifically, additional time is required to meet the new labeling requirements for EUA CCP units as either high- or low-titer, as well as to distribute current stockpile units of investigational CCP. AABB, America's Blood Centers (ABC) and the American Red Cross (ARC), which collectively represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, wish to ensure that CCP remains readily available to patients in need.

With approximately 30 days remaining to meet FDA's implementation deadline, we respectfully request the following:

1) A 90-day extension of FDA's enforcement discretion until March 1, 2021 based on the delay in release of the ICCBBA codes and other challenges outside the control of blood centers and the hospitals they supply.
2) The EUA only authorizes a single assay, the Ortho Vitros IgG assay, for titer testing to meet the new requirements for labeling high- or low-titer CCP. We are aware that multiple test manufacturers have submitted data which would enable FDA to evaluate additional testing platforms/assays for use under an amended EUA. We request timely review of data submitted to date for all testing platforms and assays and prompt authorization of tests meeting the EUA's requirements for titer testing. If no additional tests are to be authorized, please confirm that it is no longer feasible to consider use of a test other than the Ortho Vitros IgG test.

To summarize the basis of our requests with approximately 30 days remaining for implementation:

1) Blood centers are still awaiting an amendment to the EUA to determine if they may must add testing platforms/assays. While we recognize and appreciate that the requesting manufacturers and FDA are moving as quickly as possible, the resulting loss of 60 of the 90 days for implementation creates an obstacle to implementing and validating the required testing necessary to meet the new labeling

requirements for EUA CCP units as high- or low-titer, and to continue CCP access for patients under the EUA.

2) Blood centers can begin to lay the groundwork for implementation under an amended EUA only after FDA identifies testing alternatives that meet the criteria for emergency use. This transition involves substantial work to negotiate contracts, implement changes and to complete extensive validation protocols necessary for critical systems protecting blood safety. These include laboratory testing and blood establishment computer systems (BECS), as well as the development of new workflows, standard operating procedures, and staff training.
3) ICCBBA indicates the codes for CCP product labeling will not be released until November 5, 2020. To further complicate implementation, ICCBBA must now transition from "E" to "EA" product codes because the last code available, E9999, was issued this month. The implementation of "EA" codes will require substantial IT coding changes within the blood center BECS and hospital information systems to allow acceptance of CCP products using this new alphanumeric format.
4) The current inventory of CCP collected pre-EUA is not authorized for emergency use after December 1, 2020. While these CCP units can be utilized as investigational through clinical trials or eINDs, this would create administrative complexity for FDA to approve these eINDs while also complicating the process for hospitals and providers thereby limiting therapeutic options for patients with COVID-19. We are concerned the need for eINDs will be a barrier to the continued use of CCP, one of the few treatment options currently available to healthcare providers. And at this juncture, blood centers have no clear guidance to communicate to their hospital partners regarding CCP labeling, inventory management and most importantly, continuity of care. In the absence of critical details, hospitals have no ability to prepare for changes.

We urge the agency to consider these factors and to provide an extension of the deadline for implementation of the new EUA requirements thereby protecting patient access to CCP. We look forward to a timely response.

Should you have questions, please contact Sharon Carayiannis (571-340-4565, SCarayiannis@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, Liz.Marcus@redcross.org).

Sincerely,

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Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
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cc: Gary L. Disbrow, Ph.D., Acting Director
BARDA, Office of the Assistant Secretary for Preparedness and Response