



Our STN: BL 101766/5169

SUPPLEMENT APPROVAL

December 10, 2024

OneBlood, Inc.
Attention: Betsy Sasnett
1731 Riggins Road
Tallahassee, FL 32308

Dear Betsy Sasnett:

We have approved your request received June 10, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Whole Blood and blood components to manufacture the products listed below, for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment:

- Convalescent Plasma, High Titer, Anti-SARS-CoV-2 (Whole Blood-derived)
- Apheresis Convalescent Plasma, High Titer, Anti-SARS-CoV-2

We hereby approve the 18 container labels submitted under amendment #5001, dated August 21, 2024, and the addendum to your Circular of Information submitted under amendment #5004, dated November 6, 2024, which must be available for distribution with the above products.

This approval applies to your establishments listed in Attachment A, operating under U.S. License Number 1875.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Orieji Illoh, MD
Acting Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure:

- Attachment A. Establishments Information

Attachment A. Establishments Information

Registration Number	Street address	City, State
1070196	10100 Dr. Martin Luther King, Jr. Street, North	St. Petersburg, Florida
1072425	8669 Commodity Circle	Orlando, Florida
3004054586	700 Forest Point Circle	Charlotte, North Carolina