DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Esther Hernandez
President
United States Blood Bank, Inc.
2400 NW 95th Avenue
Miami, Florida 33172-2348

Dear Ms. Hernandez:

An inspection of United States Blood Bank, Inc. (USBB), 2400 NW 95th Avenue, Miami, Florida, conducted between April 29, 2015, and June 16, 2015, by the Food and Drug Administration's (FDA or the agency) Florida district office revealed deviations from Parts 211 and 600-640 of Title 21, Code of Federal Regulations (21 CFR), and the standards in your license. At the conclusion of the inspection, a seven-page, nine-item list of observations (Form FDA 483) was issued. The inspectional observations indicate that significant deviations routinely occur in important areas of your blood establishment. FDA has determined that these deviations are of a serious nature and constitute a danger to health. Deviations noted include, but are not limited to, the following:

1. Failure to make reasonable attempts to notify donors, including autologous donors, who have been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by 21 CFR § 610.41; or who have been determined not to be suitable as donors based on suitability criteria under 21 CFR §640.3 or §640.63 . You must make reasonable attempts to notify a donor within 8 weeks after determining that such donor is deferred or determined not to be suitable for donation [21 CFR 630.6(a) and (c)]. For example:

   A. Between August 19, 2013 and April 15, 2015, you failed to notify at least 120 donors who tested reactive on a screening test for human immunodeficiency virus (HIV) or reactive for HIV in addition to another communicable disease agent. Forty-seven (47) of these donors also tested positive on a confirmatory test for HIV. Your firm's attempts to notify these 120 donors were limited to the mailing of generic letters, which requested that the donors contact the blood bank, without providing any further information. No additional notification attempts were made. Only sixteen of the 120 donors have returned to the blood bank to be notified of their reactive HIV test results.

   B. Between September 2014 and February 2015, you failed to notify at least six donors who tested reactive on a screening test for hepatitis B virus (HBV) and/or hepatitis C virus (HCV).

2. Failure to adequately determine the suitability of donors as a source of Whole Blood. Donors must be in good health, as indicated in part by freedom from any infectious skin diseases at the site of phlebotomy and from any such disease generalized to such an extent as to create a risk of contamination of the blood; and freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics [21 CFR 640.3(a), (b)(5), and (b)(7)]. For example, during the inspection on April 30, 2015 and May 1, 2015, the investigators observed two separate donor screening procedures that failed to include an examination of the donors' arms prior to phlebotomy.

3. Failure to further test each donation, including autologous donations, found to be reactive by a screening test performed under paragraphs (a) and (b) of §610.40, whenever a supplemental test (additional, more specific) has been approved for such use by FDA [21 CFR 610.40(e)]. For example, your establishment has routinely received notifications from your testing laboratory that discriminatory and/or confirmatory testing cannot be performed due to an insufficient quantity of testing sample. Despite these notifications, your establishment has failed to provide additional samples so that testing could be completed and donors could be appropriately notified of all initial, discriminatory, and/or confirmatory testing results.

4. Failure to maintain records concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced [21 CFR 606.160(a)(1)]. For example:

   A. Your firm failed to maintain all records of testing for communicable disease agents since 2013, including records of Nucleic Acid Testing (NAT) discriminatory testing and/or supplemental/confirmatory testing. In addition, your firm could not provide evidence that all donors lacking these testing records have been identified for follow-up with the testing laboratory.

   B. The investigator's review of your "Alarm Company Report Logs" found that between December 2013 and April 2015, there were 11 occasions on which units of Red Blood Cells were relocated due to a refrigerator malfunction or power outage. However, your firm's records did not include documentation of the unit numbers involved or the length of time the units may have been stored outside the acceptable temperature range.

5. Failure to use equipment for the collection, processing, compatibility testing, storage and distribution of blood and blood components in the manner for which it was designed, as prescribed in the Standard Operating Procedures Manual, so as to assure compliance with the official requirements prescribed for blood and blood products [21 CFR 606.60(a)]. For example, the (b) (4), used by your firm to determine donor hemoglobin values during donor screening, is being used contrary to the manufacturer's specifications for the equipment. The manufacturer's specifications state that the

analyzer should not be operated at non-condensing humidity levels greater than (b) (4) and that operating temperatures must be between (b) (4) Your firm has been operating this analyzer outside of the appropriate temperature and/or humidity ranges, which has caused the equipment to overheat and shut off.

In addition, you failed to obtain FDA written approval to ship human blood or blood components that had a reactive screening test for evidence of infection due to a communicable disease agent(s) designated in §610.40(a) or that are collected from a donor deferred under §610.41(a), [21 CFR 610.40(h)(2)(ii)] and you failed to label the products to include the information required by 21 CFR 606.121 and 21 CFR 610.41(h). From January 2013 through December 2014, you shipped approximately 1,500 units of plasma collected from donors who tested reactive on a screening test for one or more of the following communicable disease agents: HIV (Human Immunodeficiency Virus Type 1 and Type 2), HBV (Hepatitis B Virus), HCV (Hepatitis C Virus), and (HTLV-I/II) (Human T-lymphotropic Virus, types I and II) without written FDA approval. The labeling on the units included only a Blood Unit Identification Number, the collection date, the gender of the donor, and a Biohazard sticker with the communicable disease agent handwritten on the label.

The above identified deficiencies are not intended to be an all-inclusive list of violations at your facility. The nature of the deficiencies noted during the recent inspection leads us to conclude that they are a direct consequence of your firm's disregard for the applicable regulations and standards in your license. These deficiencies also demonstrate management's failure to exercise control over the establishment in all matters relating to compliance. In addition, the inspection makes clear that management has failed in its responsibilities to assure that personnel are adequately trained and supervised, and have a thorough understanding of the procedures that they perform, as required by 21 CFR 600.10(b), 21 CFR 606.20(b), and 21 CFR 211.25 (a) and (b).

Based on all of these observations, your establishment fails to conform to the applicable standards established in your license and the regulations designed to ensure the continued safety, purity, and potency of the manufactured blood products. Accordingly, FDA has reasonable grounds to believe that grounds for revocation of U.S. license number 1229 exist under 21 CFR 601.5(b)(1)(iv), and that for those reasons your manufacturing presents a danger to health.

This letter confirms the telephone conversation in which notice was given that, pursuant to 21 CFR 601.5(b) and 601.6(a), U.S. license number 1229 issued to United States Blood Bank, Inc., for the manufacture of Whole Blood, Red Blood Cells, and Plasma, has been suspended, as of the time and date indicated below. Instructions were given at that time not to ship blood or blood components subject to license in interstate commerce.

In accordance with the regulations governing suspension of license in 21 CFR 601.6, you are required to: 1) give notice of this suspension to the selling agents and distributors to whom licensed products have been delivered within the 60 days prior to this suspension; and 2) furnish to the Office of Compliance and Biologics Quality (OCBQ), Center for Biologics Evaluation and Research, complete records of such deliveries and notices of suspension.

All communication should be directed to the attention of Ms. Mary A. Malarkey, Director, OCBQ , Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave, WO71-G112, Silver Spring, MD 20993-0002. Ms. Malarkey may be reached at (240) 402-9153. In addition, a copy of all correspondence related to this license suspension should be sent to the FDA's Florida district office, 555 Winderley Place, Suite 200, Maitland, Florida 32751, to the attention of Ms. Andrea Norwood. Ms. Norwood may be reached at (407) 475-4724.

You are advised that United States Blood Bank, Inc., U.S. license number 1229, no longer holds an unsuspended and unrevoked license for the manufacture of Whole Blood, Red Blood Cells, and Plasma, and that unless and until otherwise notified, introduction or delivery for introduction into interstate commerce of such products is a violation of section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]. Additionally, any shipments made during the suspension of this license may constitute a violation of the Federal Food, Drug, and Cosmetic Act, [see, for example, 21 U.S.C. 331(a)]. Criminal penalties may be imposed for such violations of the Public Health Service Act and Federal Food, Drug, and Cosmetic Act. No shipments of blood and blood components labeled with your U.S. license number may be made during the suspension of license. This license suspension does not prohibit you from procuring blood and blood components from another acceptable source in order to meet the needs of your community, provided that all appropriate controls are exercised to ensure proper storage and distribution conditions. You are advised, however, that blood products procured from alternate sources and intended for interstate distribution must be U.S. licensed products.

The Commissioner will proceed pursuant to 21 CFR 601.5(b)(1) to revoke U.S. license number 1229 for the manufacture of Whole Blood, Red Blood Cells, and Plasma, unless you: 1) telephone Ms. Malarkey within ten (10) working days of receipt of this letter, to request that the matter of revocation be held in abeyance pending resolution of the matters involved, as provided in 21 CFR 601.6(b)(2), and confirm the telephone call in writing; and 2) notify Ms. Malarkey in writing of the specific actions taken to correct all deficiencies noted in this letter and on the Form FDA 483 issued at the conclusion of the most recent inspection of your facility. Any request that revocation be held in abeyance will be evaluated by OCBQ and the Florida district office.

Number SF-001-15 has been assigned to this suspension. All correspondence with OCBQ concerning this suspension should reflect this number. The appropriate state officials will also be notified of your license suspension.

Sincerely,

Karen Midthun, M.D.
Director
Center for Biologics Evaluation and Research

Effective Date 7-9-15 Time 9:30AM