US Label Examples of Product Types Needed for FDA Review

1. Whole Blood with CPD

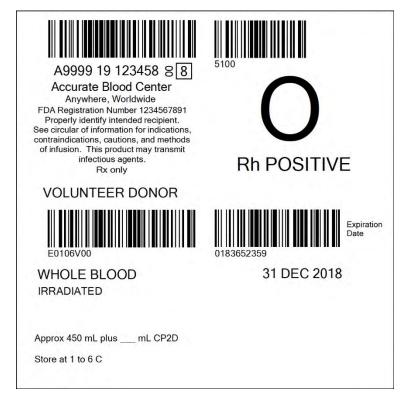


2. Whole Blood with CPDA-1

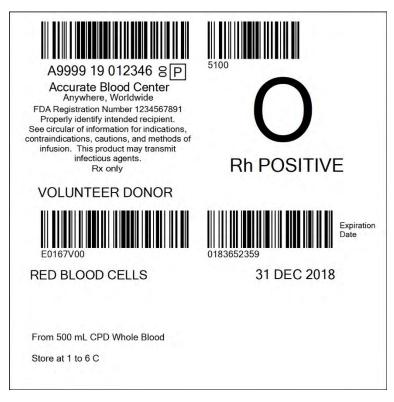


US Label Examples of Product Types Needed for FDA Review

3. Whole Blood with CP2D



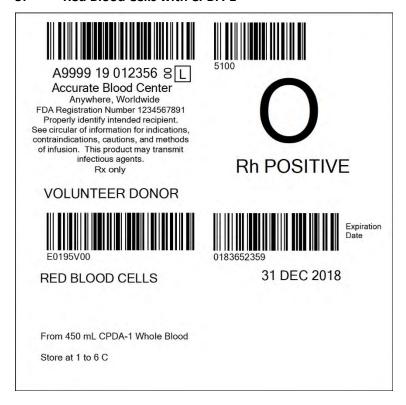
4. Red Blood Cells with CPD



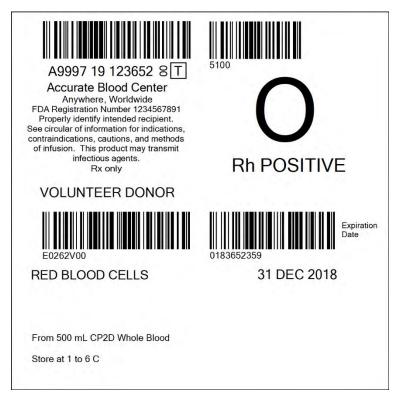
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US Label Examples of Product Types Needed for FDA Review

5. Red Blood Cells with CPDA-1



6. Red Blood Cells with CP2D



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US Label Examples of Product Types Needed for FDA Review

7. Red Blood Cells – Additive Solution

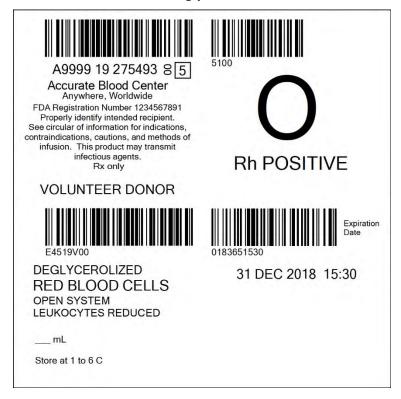


8. Red Blood Cells – Frozen



US Label Examples of Product Types Needed for FDA Review

9. Red Blood Cells – Deglycerolized



10. Red Blood Cells – Leukocytes Reduced



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US Label Examples of Product Types Needed for FDA Review

11. Red Blood Cells – Irradiated



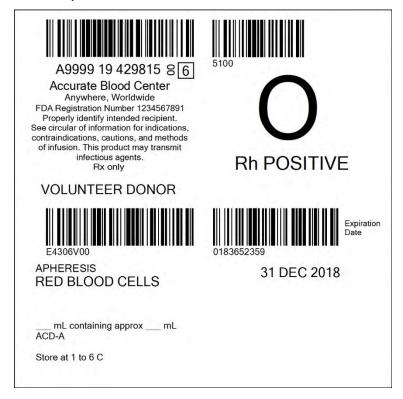
12. Red Blood Cells – Leukocytes Reduced and Irradiated



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US Label Examples of Product Types Needed for FDA Review

13. Apheresis Red Blood Cells



14. Apheresis Red Blood Cells – Leukocytes Reduced



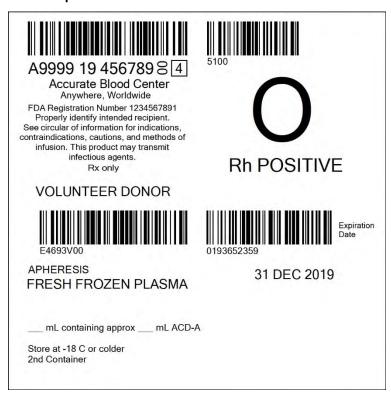
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US Label Examples of Product Types Needed for FDA Review

15. Fresh Frozen Plasma



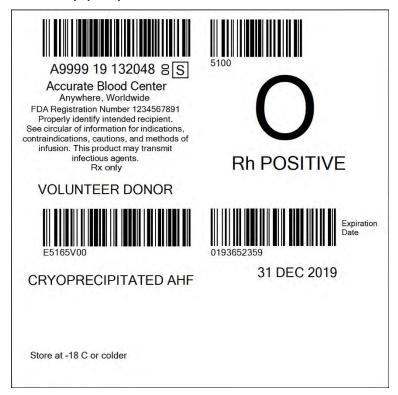
16. Apheresis Fresh Frozen Plasma



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US Label Examples of Product Types Needed for FDA Review

17. Cryoprecipitated AHF



18. Source Leukocytes



Note:

The label must reflect the results of any tests that have been completed before shipment of the product and must also indicate any tests not completed before shipment.

See 21 CFR 610.40(g)(2) and 606.121(h).

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US Label Examples of Product Types Needed for FDA Review

19. Platelets



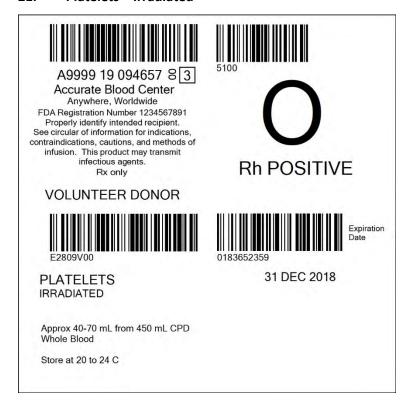
20. Platelets – Leukocytes Reduced



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US Label Examples of Product Types Needed for FDA Review

21. Platelets – Irradiated



22. Apheresis Platelets



US Label Examples of Product Types Needed for FDA Review

23. Apheresis Platelets – Irradiated



24. Apheresis Platelets – Leukocytes Reduced



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US Label Examples of Product Types Needed for FDA Review

25. Apheresis Platelets – Leukocytes Reduced and Irradiated



26. Source Plasma

Collected from a normal donor using

an automated method. Store at -20 C or colder

50 to 120 mL 4% Na Citrate solution by



Note:

Not all Source Plasma is tested for anti-HBc. If the Source Plasma has not been tested, then the statement "Not tested for anti-HBc" or "Not tested for antibodies to HBc" must be printed on the label.

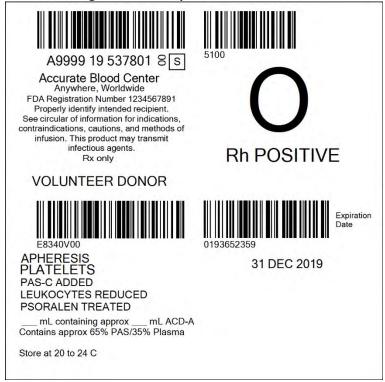
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nonreactive for HBsAq, HCV

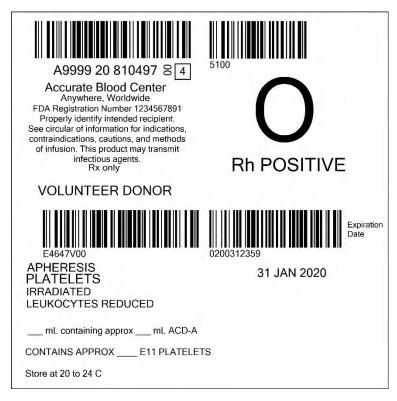
RNA, HBV DNA, and HIV-1 RNA.

US Label Examples of Product Types Needed for FDA Review

27. Pathogen Reduced Apheresis Platelets



28. Low Yield Platelets



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US Label Examples of Product Types Needed for FDA Review

29. Pooled Platelets

A9999 20 810497 8 4 Accurate Blood Center Anywhere, Worldwide FDA Registration Number 1234567891 Properly identify intended recipient. See circular of information for indications, contraindications, cautions, and methods of infusion. This product may transmit infectious agents. Rx only	POOLED ABO POOLED Rh
VOLUNTEER DONOR	. characteristics
E2897V00	Expiration Date / Time
POOLED PLATELETS OPEN SYSTEM	31 JAN 2020 17:35
mL Number of units in pool	
Anticoagulants present From Whole Blood	
Store at 20 to 24 C	

30. Pooled Cryoprecipitated AHF

